Florida
MEDS-AD Waiver

Annual Report
Demonstration Year 11
January 1, 2016 – December 31, 2016

1115 Research and
Demonstration Waiver
#11-W-00205/4

This page intentionally left blank

Table of Contents

This page intentionally left blank

MEDS-AD Waiver

Annual Report

The State must submit an annual report documenting accomplishments, project status, quantitative and case study findings, interim evaluation findings, utilization data, and policy and administrative difficulties in the operation of the Demonstration. This report must also contain a discussion of the items that must be included in the quarterly reports required under paragraph 24. The State must submit this report no later than 90 days after the close of each Demonstration Year.

This report is the annual report for Demonstration Year (DY) 11 covering the period of January 1, 2016, through December 31, 2016. For detailed information about the activities that occurred during previous quarters of the demonstration, please refer to the quarterly and annual reports at http://ahca.myflorida.com/medicaid/MEDS-AD/index.shtml.

Federal Waiver Authority

On June 30, 2015, the State submitted a 3-year extension request to The Centers for Medicare and Medicaid Services (CMS) for the period January 1, 2016 through December 31, 2018. The State is currently operating under a temporary extension through May 28, 2017.

Budget Neutrality Update

The following table compares actual MEDS-AD Waiver expenditures to the costs projected for this population had the MEDS-AD Waiver not been granted. To date, actual expenditures continue to be below the projected cost.

Budget Neutrality MEDS-AD Waiver							
Demo Year	**Quarter Ended**	**With Waiver Expenditures ($)***	**With Waiver Expenditures Cumulative Total ($)**	**Without Waiver (Target) Expenditures ($)**	**Without Waiver Expend Total ($)**	**Difference ($)**	**Cumulative Difference ($)**
DY1	Q1	51,696,950		507,710,894		456,013,944	
	Q2	132,235,096		507,710,894		375,475,798	
	Q3	105,271,113		507,710,894		402,439,781	
	Q4	146,356,839	435,559,998	507,710,894	2,030,843,575	361,354,055	1,595,283,577
DY2	Q5	69,927,763		460,700,626		390,772,863	
	Q6	79,047,475		460,700,626		381,653,151	
	Q7	87,567,517		460,700,626		373,133,109	
	Q8	90,210,963	762,313,716	460,700,626	3,873,646,079	370,489,663	3,111,332,363
DY3	Q9	93,882,619		455,999,599		362,116,980	
	Q10	103,108,178		455,999,599		352,891,421	
	Q11	95,761,142		455,999,599		360,238,457	
	Q12	96,128,169	1,151,193,824	455,999,599	5,697,644,476	359,871,430	4,546,450,652
DY4	Q13	107,727,900		465,401,653		357,673,753	
	Q14	106,365,677		465,401,653		359,035,976	
	Q15	120,849,499		465,401,653		344,552,154	
	Q16	133,665,863	1,619,802,762	465,401,653	7,559,251,086	331,735,790	5,939,448,324
DY5	Q17	138,153,082		460,700,626		322,547,544	
	Q18	144,229,555		460,700,626		316,471,071	
	Q19	134,966,909		460,700,626		325,733,717	
	Q20	148,599,566	2,185,751,874	460,700,626	9,402,053,590	312,101,060	7,216,301,716
DY6	Q21	154,004,876		**			
	Q22	146,340,361		**			
	Q23	155,268,617		**			
	Q24	163,774,246		**	9,402,053,590		6,596,913,616
DY7	Q25	165,396,338		**			
	Q26	184,629,761		**			
	Q27	165,063,579		**			
	Q28	168,922,270	3,489,151,922	**	9,402,053,590		5,912,901,668
DY8	Q29	151,084,893		**			
	Q30	150,685,372		**			
	Q31	159,986,109		**			
	Q32	165,422,402	4,116,330,697	**	9,402,053,590		5,285,722,893

Budget Neutrality MEDS-AD Waiver							
Demo Year	**Quarter Ended**	**With Waiver Expenditures ($)***	**With Waiver Expenditures Cumulative Total ($)**	**Without Waiver (Target) Expenditures ($)**	**Without Waiver Expend Total ($)**	**Difference ($)**	**Cumulative Difference ($)**
DY9	Q33	164,516,691		**			
	Q34	161,043,862		**			
	Q35	147,278,798		**			
	Q36	124,678,137	4,713,848,186	**	9,402,053,590		4,688,205,404
DY10	Q37	134,213,827		**			
	Q38	113,860,203		**			
	Q39	113,106,218	5,075,028,434	**	9,402,053,590		4,327,025,156
	Q40	115,046,182	5,190,074,616	**	9,402,053,590		4,211,978,974
DY11	Q41	123,730,211	5,313,804,828	**	9,402,053,590		4,088,248,762
	Q42	185,366,376	5,499,171,204	**	9,402,053,590		3,902,882,386
	Q43	354,179,282	5,853,350,486	**	9,402,053,590		3,548,703,104
	Q44	147,101,428	6,000,451,914	**	9,402,053,590		3,401,601,676

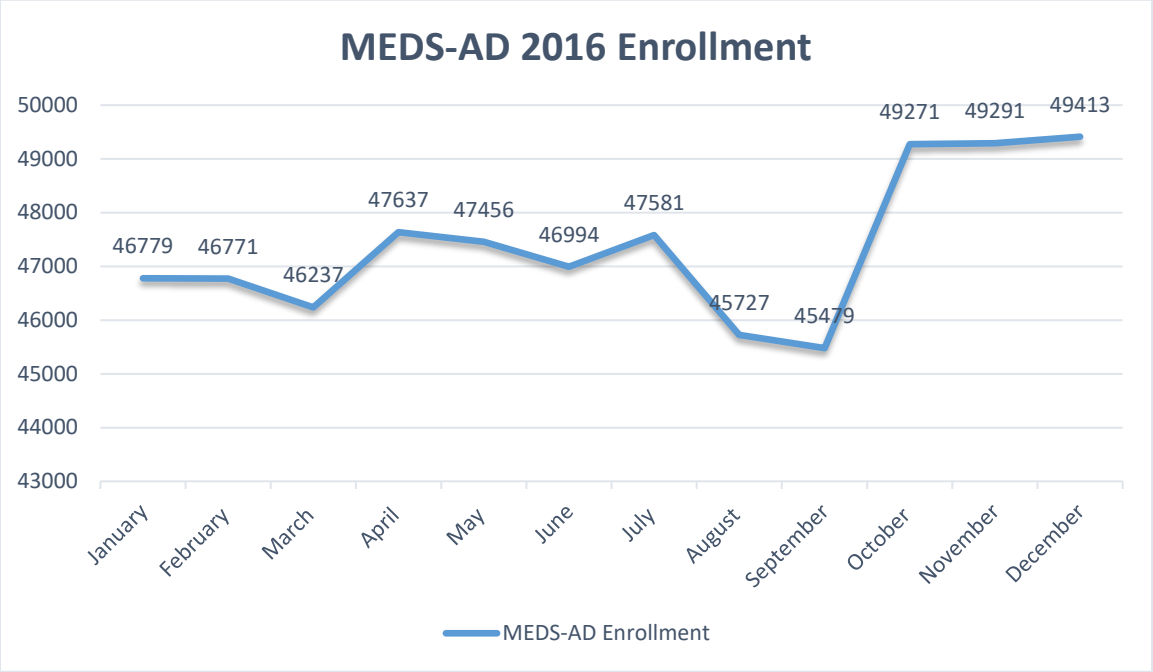
*These are based on dates of payment expenditures for the MEDS-AD Waiver reported within the CMS64, which could get distributed across the demonstration years.

**The original without waiver expenditure ceiling was not increased with the renewal period beginning in Quarter 21. The $7,216,301,716 cumulative difference between the approved budget neutrality ceiling and actual waiver expenditures as of the end of the original demonstration period on December 31, 2010, was allocated across the 12 renewal quarters as the new expenditure ceiling.

Operational Update

Eligibility and Enrollment[1]

Enrollment in the MEDS-AD Waiver increased by 5.6% during DY 11.



[1] Total enrollment counts are revised for retroactive eligibility determinations, and therefore may change from one reporting period to the next.

Medication Therapy Management Program

Comprehensive Medication Reviews

The University of Florida provides quarterly case review activity reports to the Agency. These reports include details of case review statuses, patient-specific intervention results, listing of interventions faxed to prescribers, and a tabulation of the results of the interventions by clinical category. Case review activity reports for DY 11 can be found in the MEDS-AD Quarterly reports posted on the Agency's Web site at http://ahca.myflorida.com/medicaid/MEDS-AD/quarterly.shtml

Evaluation

The Agency contracts with Florida State University (FSU) to conduct an independent evaluation of the Medication Therapy Management program for the MEDS-AD Waiver. The Agency and FSU executed a new three-year contract on October 6, 2016.

See Attachment I for the Medication Therapy Management (MTM) program evaluation final report for DY 10 from Florida State University, dated February 22, 2017. The report provides a summary of the findings of the MTM program for the pre-MTM intervention period (June 1, 2014 through May 31, 2015).

The overall results of the MTM program are positive with the majority of participants taking their medication correctly and as prescribed. The Agency's evaluation team communicated findings and recommendations from FSU to the MTM program administrators for consideration.

Data Mining

Data Mining Activities are no longer under the authority of this waiver. On June 20, 2016 Florida's Medicaid Fraud Control Unit (MFCU) received approval from the Office of Inspector General to conduct data mining under Title 45 CFR, Section 1007.20(a).

Data Mining Activities

During the period January through June 2016, the following MFCU initiatives resulted from the data mining activities approved through the MEDS-AD waiver.

- Opened two new complaints under Data Mining Analyst Report (DMAR)-19
- Opened one new complaint under DMAR - 37
- Closed one complaint
- Made three referrals to the Agency (two under DMAR-70 and one under DMAR-26)

Attachment I
DY 10 Final Evaluation Report

Deliverable #4

MEDS-AD Waiver Medication Therapy Management (MTM) Program Evaluation Final Report – 2015 (DY 10)

Prepared for Florida Medicaid

In Partial Fulfillment of Contract MED185

College of Medicine

Florida State University

February 22, 2017

Table of Contents

Executive Summary

Overview

The goals of the Florida Medicaid Medication Therapy Management (MTM) program are far-reaching: to improve the quality of care and prescribing practices based on best-practice guidelines, to improve patient adherence to medication plans, to reduce clinical risk, and to lower prescribed drug costs and the rate of inappropriate spending for certain Medicaid prescription drugs. The program was implemented in a high-risk population of Medicaid recipients eligible through Florida's Section 1115 MEDS-AD Research and Demonstration Waiver.

This report summarizes the findings of the pre-MTM intervention period (June 1, 2014 through May 31, 2015) and the MTM intervention period (June 1, 2015 through May 31, 2016). The MTM intervention period in this report is referred to as Year 5 Cohort 5 (Cohorts 1-4 were previously evaluated). Year 5 Cohort 5 MTM program participants are compared with Medicaid recipients who were members of the MEDS-AD Waiver population (MEG1) but either declined the opportunity to participate or were never contacted about the opportunity.

Quantitative Results

Congruent with evaluations of the previous four cohorts, the results of the quantitative analysis of the Florida Medicaid MTM program for Cohort 5 indicate no statistically significant improvements in the intervention group when contrasted with a comparison group of non-participants. This result was anticipated by the evaluation team, since most recipients were already adhering to their medication plans. Despite these null findings, the results are positive in the sense that it appears the vast majority of MEDS-AD recipients demonstrate high levels of medication adherence.

Qualitative Results

The qualitative evaluation is a thematic analysis of transcripts of audio files of the Comprehensive Medication Review (CMR) calls between University of Florida, College of Pharmacy (UF COP) pharmacists and MTM program participants. Thus, it is an examination of the intervention that allows for a deeper understanding of the context of the CMRs, the CMR delivery, and the pharmacists' skills. In addition to describing the components of the CMR, this evaluation demonstrates that participants value components of the MTM program including learning about medications, caring pharmacists and medication lists. Participants indicate that the CMR assists them in various ways, specifically increasing their understanding of medications, knowledge about health care, and confidence

and self-efficacy about their health care. Overall, participants overwhelmingly rated the MTM program favorably and indicated it was helpful. The few participants who reported the program was not helpful for understanding their medication said they previously felt well-informed and had no need for further knowledge.

Report Prepared By:

Principal Investigator	Henry J. Carretta, PhD
Evaluation Team	Lisa Schelbe, PhD
	Jeff Lacassee, PhD
	Naomi Brownstein, PhD
	Kelsey Houser, MA
	Katelyn Graves, PhD
	Melissa Murphy, MA
	Michael P. Smith, MA, MPA
	Karen W. Geletko, MPH

List of Tables

List of Terms, Acronyms, and Abbreviations

Term, Acronym or Abbreviation	Explanation
ACEI	Angiotensin-Converting-Enzyme inhibitor
AHCA	Florida Agency for Health Care Administration (the Agency)
AHFS	American Hospital Formulary Service
ARB	Angiotensin Receptor Blockers
CCC	Chronic condition count
CMR	Comprehensive Medication Review
COPD	Chronic obstructive pulmonary disease
Crossover Participant	Any MEDS-AD waiver recipient who participated in a previous MTM intervention (cohorts 1-4)
DTP	Drug Therapy Problem
EENT	Ear, eye, nose, and throat
EQ	Evaluation Question
FSU	Florida State University
GERD	Gastroesophageal Reflux Disease
GSDD	Gold Standard Drug Database
HCBS	Home and Community-Based Services
LCL	Lower Confidence Interval Limit
LTC	Long-term Care
MAP	Medication Action Plan
Max.	Maximum
MCO	Managed Care Organization
MEDS-AD	Florida's Section 1115 MEDS-AD Research and Demonstration (Project No. 11-W-00205/4).
MEG1	Medicaid eligible population number one. A category of persons eligible for Medicaid under the MEDS-AD Waiver.
Min.	Minimum
MPR	Medication Possession Ratio – a medication adherence measure
MRX	Pharmacy-based component of UCSD's Chronic Illness and Disability Payment System risk adjustment system
MTM	Medication Therapy Management
MTM-NP	Medication Therapy Management non-participants
MTM-P	Medication Therapy Management Participants
N or Num.	Number, as in number of recipients or events
OTC	Over-the-counter
Participant	Any Medicaid recipient who participated in the most recent MTM program intervention, i.e., has completed a CMR with the UF COP staff in cohort 5
PCP	Primary Care Physician/Provider

Term, Acronym or Abbreviation	Explanation
PDC	Proportion of Days Covered – a medication adherence measure
Recip./recipient	Any person enrolled in Florida Medicaid
Rx	Medication
SP-INT	Study Period Intervention
SP-PRI	Study Period Pre-Intervention
Std. Dev.	Standard Deviation
UCL	Upper Confidence Interval Limit
UCSD	University of California San Diego
UF COP	University of Florida College of Pharmacy

Introduction

This report summarizes the findings of the evaluation of the Florida Medicaid Medication Therapy Management (MTM) program implemented by the University of Florida (UF) College of Pharmacy (COP) for the pre-MTM intervention period (June 1, 2014 through May 31, 2015) and MEDS-AD Waiver MTM intervention period (June 1, 2015 through May 31, 2016). Medicaid does not typically cover MTM services, and the recipients included in this evaluation were adults who are often ineligible for Medicaid. Recipient eligibility for Medicaid and approval for the MTM program was achieved through a Section 1115 MEDS-AD Research or Demonstration Waiver approved by the Centers for Medicare and Medicaid Services. The waiver is referred to as the MEDS-AD Waiver in this document.

Demonstration waivers under Section 1115 allow states flexibility to design and improve Medicaid programs by expanding coverage to individuals not otherwise covered by Medicaid, thereby providing services not typically available to these recipients. The MEDS-AD Waiver defines three distinct populations. This evaluation only relates to a population designated in this report as MEG1. Eligibility criteria for the evaluated population includes individuals eligible for Medicaid but not eligible for Medicare and who are eligible for but not currently receiving: 1) long-term institutional care, 2) hospice services in the home or a facility, 3) home and community-based services (HCBS), or 4) coverage under a contract with a managed care organization (MCO). Eligibility criteria also include limits on the recipients' income and assets. All MEG1 Florida Medicaid recipients were eligible for but not all received MTM services.

Background on the MTM Program and Evaluation

The goals of the MTM program are to improve the quality of care and prescribing practices based on best-practice guidelines, to improve patient adherence to medication plans, to reduce clinical risk, and to lower prescribed drug costs and the rate of inappropriate spending for certain Medicaid prescription drugs for a high-risk population of Medicaid recipients eligible through the MEDS-AD Waiver.

The active intervention study periods for previously evaluated cohorts were: Cohort 1) June 1, 2011 to May 31, 2012, Cohort 2) June 1, 2012 to May 31, 2013, Cohort 3) June 1, 2013 to May 31, 2014 and Cohort 4) June 1, 2014 to May 31, 2015. The intervention period for the current Cohort 5 was June 1, 2015 to May 31, 2016. Only the first seven months of the Cohort 5 intervention period were included in this study for the evaluation questions (EQ) involving comparisons of MTM intervention participants (MTM-P) and non-participants (MTM-NP) due to the unavailability of complete and final pharmacy data

from January 2016 and beyond.[1] Each intervention study period is preceded by a pre-intervention period of 12 months in order to contrast MTM program metrics before and after the intervention Comprehensive Medication Review (CMR). The evaluation team's analysis contrasted the MTM-P group with MEG1 members that were not recruited into the intervention group and remained in the study pool after applying the inclusion-exclusion criteria detailed in Appendix I. These recipients make up the non-participant group and are referred to as "MTM-NP" throughout this report. Therefore, Cohort 5's MTM-P and MTM-NP comparison groups were followed for up to 19 months; the cohort was comprised of a large sample of recipients who maintained eligibility for MEDS-AD on a monthly basis as defined by the MEDS-AD Waiver for the MEG1 population.

Recruitment of the Intervention Population

Selection of MEG1 recipients covered by the MEDS-AD Waiver to participate in the MTM intervention was a multistep process conducted by the University of Florida, College of Pharmacy (UF COP), the MTM program provider. Consent was obtained at two points in time for targeted Medicaid recipients. "Selection" refers to processes used by the Agency and UF COP to produce a list of recipients for initial contact, from which a subset of these recipients provided their consent to participate in the MTM program. The Agency did not "select" MTM participants; they created a list of eligible recipients that was provided to UF COP (see *Selection Process* in Appendix I for more information). In essence, recipients self-selected into the intervention. Recipients who opted into the intervention and ultimately completed a CMR formed the study's nominal MTM-P population.

Study Group Dynamics

Cohort 5's MEDS-AD Waiver MEG1 population at the core of this evaluation was a dynamic group with membership changing frequently due to lost or reinstated eligibility under the MEDS-AD Waiver throughout the course of the observation period. MEG1 population members sometimes transitioned in and out of the eligible study population. Recipients who received the intervention with past Cohorts 1-4 were identified and excluded from eligibility in subsequent comparison groups. Eligible MEG1 recipients who were never exposed to the intervention may have served as a member of a comparison group in previous Cohorts 1-4.

[1] AHCA allows for a 12-month claims submission period and an additional year for resolving any formal disputes via their adjudication process. Consequently, the claims period in this report was limited to the end of calendar year 2015 in an attempt to mitigate adverse effects of claims run-out.

UF COP Intervention and Data Collection Processes

Recipients in Cohort 5 were required to provide additional consent via telephone and ultimately complete an interview with trained staff from the UF COP before entering into the study's intervention population. UF COP staff members conducted a CMR during the initial interview as the first step in the intervention. A CMR involves collecting patient specific information on prescription medications and potential medication related problems, which if evident, entails creating an action plan to resolve those problems. Based on findings from the CMR, UF COP staff had the option to: 1) send the patient a Medication Action Plan (MAP), which included a medication list and possibly recommendations for behavioral change relevant to their condition and medication, and/or 2) send a facsimile to the recipient's reported primary care provider (PCP) with recommendations for changes in medication. Any given intervention for the recipient may have included a MAP only, a PCP FAX only, a MAP and a PCP FAX, or none of the post-CMR actions. Recommended actions were based on a pharmacist's expert opinion regarding over- or under-utilization of medication, medication interactions, or other issues related to the patient's treatment. The PCP may or may not have implemented recommendations the pharmacist offered. Subsequent to the CMR and post-CMR actions, UF COP followed participants for an additional nine months. UF COP staff conducted reviews of patient medication claims records provided by the Pharmacy Benefit Management vendor for Florida Medicaid to determine if recommendations had been implemented or new problems had appeared. Occasionally, the quarterly reviews lead to another patient or PCP contact, which also may determine whether the recommendations were implemented.

Quantitative and Qualitative Study Evaluation Questions Addressed in this Report

Quantitative and Qualitative Evaluation Questions (EQ) addressed in this report are listed in Table 1.

Table 1. Evaluation questions addressed in this report, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Evaluation Question Number	Quantitative Evaluation Questions
EQ 1	What is the level of medication adherence in the MTM participants 30 to 60 days after the CMR as compared with baseline measure at CMR?
EQ 2	What are the differences in the Pre-MTM intervention and MTM intervention periods between MTM participants and all other eligible waiver recipients for medication adherence?
EQ 3	How many and what type of recommendations for medication change are made by the UF COP staff for the MTM participants?
EQ 4	How many recommendations for medication change are adopted in the intervention period by the MTM participants and their providers?
EQ 5	What are the demographic characteristics of MTM participants compared to all other eligible waiver recipients, and are there any significant differences?
Evaluation Question Number	**Qualitative Evaluation Questions**
EQ 6	What do participants perceive to be the most valuable components of the MTM program?
EQ 7	How do participants perceive that the CMR assists them? (e.g., How does the CMR impact participants' ability to understand medications, take a more active part in their care, and understand the questions to ask their doctor or when to contact their doctor?)
EQ 8	How do participants rate the overall care they experienced in the MTM program?
EQ 9	What are the components of the CMR provided by the UF COP pharmacists? (e.g., How is the CMR implemented?)

Study Methods-Abridged

Detailed quantitative and qualitative study methods may be found in Appendices I and II, respectively. The evaluation was approved by the Florida State University (FSU) Institutional Review Board and by the Agency for Health Care Administration (AHCA) Privacy Office. The MTM intervention services contract was reviewed by the AHCA Privacy Office.

Overall Study Design

The overall study design used quantitative and qualitative methods to address the EQs above. Quantitative analysis was based principally on secondary administrative data provided by the Agency and was supplemented by primary data that the UF COP collected during the MTM intervention. Primary data for the qualitative analysis was collected via telephone interviews with recipients, and these responses represented their retrospective opinions of the MTM intervention. Some interviews with UF COP program staff were also conducted as part of the qualitative analysis.

Quantitative Design

This study uses a retrospective observational examination with non-equivalent comparison groups of all Medicaid covered prescription drug services provided to the study population for the period June 1, 2014 through December 31, 2015 (19 months). Retrospective data collected by UF COP from August 30, 2015 through May 31, 2016 for MTM participants only was also used. The principle comparisons, addressed in EQ2, evaluate medication adherence measures for MTM-P versus MTM-NP after applying inclusion-exclusion criteria, as outlined in Table 2 below. Analysts used pharmacy encounter records and claims data to address EQ2. EQ5 compares the MTM-P and MTM-NP populations on demographic measures after applying the inclusion-exclusion criteria to examine any potential selection bias. Analysts used demographic and programmatic eligibility files for the MEG1 population to compare the demographic characteristics of the MTM intervention group with the MTM-NP population. EQ1 addresses adherence for the MTM-P based on UF-COP's adherence assessments. Medication adherence for EQ1 and EQ2 was measured somewhat differently, but each method considers possession of the prescription by the patient based on fill dates and the number of doses provided to determine adherence levels over an observed period. EQ3 and EQ4 examine UF COP's recommendations for medication changes and resolution rates for those who participated in the intervention as well as additional lifestyle issues identified during the CMRs. EQ3 and EQ4 were addressed by reviewing the

patient-level data and quarterly reports provided by UF COP. The study population for EQ1, EQ3, and EQ4 nominally includes all MTM-P.

Qualitative Design

This evaluation used audio recordings of telephone calls between UF COP pharmacists and MTM participants. There was a total population of 156 CMR calls. The 94 calls that were at least 20 minutes in length were purposively sampled. A random subsample of 33 valid calls drawn from the 94 calls were transcribed and then analyzed. Table 2 contains the demographics for these CMR calls.

Table 2. Demographics of CMR sample.

Demographic Variable	Sample Composition
Gender	48.5% Female (n=16) 51.5% Male (n=17)
Race/Ethnicity	15.2% Black (n=5) 9.1% Hispanic (n=3) 15.2% Not identified (n=5) 6.1% Other (n=2) 54.5% White (n=18)
Age	Mean=52.1 years (SD=9.8)
Primary Language English	97.0% (n=32)

From the total population of 156 calls, the evaluation team (ET) randomly selected 47 calls for analysis of quality assurance questions asked at the conclusion of the CMR calls. The quality assurance questions ask participants about their perceptions of the helpfulness of the appointment and if the conversation with the pharmacist clarified any concerns with their medication. The demographics of this sample are listed below in Table 3.

Table 3. Demographics of the quality assurance questions from the CMR calls sample.

Demographic Variable	Sample Composition
Gender	57.4% Female (n=27) 42.6% Male (n=20)
Race/Ethnicity	2.1% Asian (n=1) 12.8% Black (n=6) 17.0% Hispanic (n=8) 14.9% Not identified (n=7) 6.4% Other (n=3) 46.8% White (n=22)
Age	Mean=54.64 years (SD=6.3)
Primary Language English	97.9% (n=46)

From a population of 78 participants' 30 to 60-day follow-up calls, the ET randomly selected 36 calls for analysis of quality assurance questions in the 30 to 60-day follow-up calls. The quality assurance questions asked focused on the medication list mailed to the participants after the CMR call. The demographics of this sample are found below in Table 4.

Table 4. Demographics of quality assurance questions in the 30 to 60-day follow-up calls sample.

Demographic Variable	Sample Composition
Gender	44.4% Female (n=16) 55.6% Male (n=20)
Race/Ethnicity	2.8% Asian (n=1) 8.3% Black (n=3) 8.3% Hispanic (n=3) 22.2% Not identified (n=8) 5.6% Other (n=2) 52.8% White (n=19)
Age	Mean=55.4 years (SD=6.7)
Primary Language English	100% (n=36)

Quantitative Evaluation Findings

Inclusion-Exclusion Criteria (EQ2 and EQ5 only)

Table 21 in Appendix I details the inclusion-exclusion criteria used to limit the study population for EQ2 and EQ5, first, identifying recipients who were eligible for MEDS-AD based on the criteria listed in the MEDS-AD Waiver, then, limiting the population to those with complete pharmacy claims histories. These actions were taken to ensure valid comparisons between adherence measures for MTM-P versus MTM-NP. 588 persons (24 from the MTM-P group and 564 from the MTM-NP group) from the nominal study population were excluded from analyses for EQ2 and EQ5, leaving 134 and 2,878 persons in the MTM-P and MTM-NP groups, respectively. After applying these exclusions, 84.8% of the nominal population of 158 MTM-P remained, and 83.6% of the nominal population of 3,442 MTM-NP remained. Table 5 presents a summary of this information.

Table 5. Cohort 5 nominal study population and EQ2 and EQ5 study population after applying inclusion-exclusion criteria, Florida MTM program evaluation, June 1, 2014-May 31, 2016.

	MTM-P		MTM-NP		Combined	
	Count	Percentage	Count	Percentage	Count	Percentage
Included (EQs 2 & 5)	134	84.8%	2,878	83.6%	3,012	83.7%
Excluded (EQs 2 & 5)	24	15.2%	564	16.4%	588	16.3%
Nominal	158	100%	3,442	100%	3,600	100%

Enrolled Days in the MEDS-AD Waiver

Table 6 presents the total enrolled days by study group for the MTM-P and MTM-NP populations by study period after application of the inclusion-exclusion criteria. Enrollment durations were calculated for the entire nominal yearlong pre-intervention (PRI) and intervention (INT) periods. The mean enrollment duration of a little over 7 months for MTM-P in the pre-intervention period (219 days on average) is lower than the mean enrollment duration of approximately 9 months for MTM-NP (275 days on average). This significant discrepancy is likely due to efforts to recruit newer MEDS-AD enrollees into the intervention group in order to facilitate complete observation windows during the intervention period. The difference in enrollment duration was much lower in the intervention period with 265 days and 281 days average enrollment for MTM-P and MTM-NP, respectively.

Table 6. Summary statistics for length of enrollment for recipients after applying EQ2 and EQ5 inclusion-exclusion criteria for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Study Group	Study Period	Num. Recips.	Mean Enrolled Days	Std. Dev.*	Min.	Median	Max.	Mean 95% LCL*	Mean 95% UCL*
MTM-P	SP-PRI	134	219	89	61	212	365	204	234
MTM-NP	SP-PRI	2,878	275	98	0	304	365	271	278
Combined	SP-PRI	3,012	272	98	0	304	365	269	276
MTM-P	SP-INT	134	265	120	30	334	365	245	286
MTM-NP	SP-INT	2,878	281	113	30	365	365	277	285
Combined	SP-INT	3,012	280	113	30	365	365	276	284
MTM-P	Combined	134	484	143	122	485	730	460	508
MTM-NP	Combined	2,878	556	156	62	577	730	550	561
Combined	Combined	3,012	552	156	62	577	730	547	558

*Std. Dev.=Standard Deviation, LCL=Lower Confidence Interval Limit, UCL=Upper Confidence Level Limit

Quantitative findings for EQ1 through EQ5 follow and are organized by consecutive tables numbered 7 through 19 in the main body of the report. Key findings are presented as bullets above each table name and number.

EQ1: What is the level of medication adherence in the MTM participants 30 to 60 days after the CMR as compared with baseline measure at CMR?

Based on the UF COP pharmacy records and patient-reported information, adherence indicators (yes/no) were available for each maintenance medication for MTM participants. For each medication, UF COP first calculates if there has been more than a 10-day gap between the fills of the medication. If a participant had a coverage gap of at least ten days, then UF COP also calculates the proportion of days covered (PDC) for the medication and checks if the PDC exceeds 0.8. Finally, UF COP asks patients additional questions about adherence, such as the length of time on the medication, the frequency and dosage, whether or not the patient uses memory aids for the medication, and if the patient often forgets to take their medication. A patient was considered non-adherent on their medication if they had a coverage gap of at least ten days and had a PDC below 80%. In addition, UF noted a lack of adherence if the patient reported an adherence problem with their medication(s) during their individual interview.

Adherence levels were calculated for each participant based on the proportion of their medications that were considered adherent. UF did not calculate adherence levels for medications

prescribed on an irregular basis; these medications were excluded from all calculations. Dates were not available for the adherence scores in the UF COP charts, so measures could not be compared by time period. Given this data limitation, the FSU program evaluation team was unable to respond to the EQ as originally intended. Instead, descriptive statistics were produced based on participant-level medication adherence levels during the entire June 1, 2015 to May 31, 2016 time period. FSU contacted UF COP several times during the analysis stage to request the timing (baseline or post-CMR) of each adherence score. However, the limitations of UF COP's new system, unknown to FSU at the time the evaluation questions were finalized, records the last fill date of the prescription, not the date when UF COP staff assessed adherence, and in the end, UF COP was unable to retroactively determine that date.

Interpretation of Descriptive Tables for EQ1

Adherence measures were available for 151 participants as shown in Table 7. Seven participants with a CMR did not have any records in the medication adherence file.

- While participant level adherence ranged from 0 to 100 percent, the vast majority of participants (96%) demonstrated full adherence to their medications.
- Two participants demonstrated high but imperfect adherence, at 89% and 82%.
- Of the 3 participants (2%) with low levels of adherence to their medications, one displayed 50% adherence, while the other two displayed 0% adherence.

Table 7. Summary statistics on MTM-Ps' medication adherence levels aggregated for the entire program year, Florida MTM program evaluation, June 1, 2015 - May 31, 2016.

Adherence level (percentage of medication fills considered adherent)	Number of participants per adherence level	Percentage of participants per adherence level
0	2	1.3
50	1	0.7
82	1	0.7
89	2	1.3
100	145	96.0

EQ2: What are the differences in the Pre-MTM intervention and MTM intervention periods between MTM participants and all other eligible waiver recipients for medication adherence?

Interpretation of Descriptive Tables for EQ2

Medication Possession Ratios (MPRs) and Proportions of Days Covered (PDCs) are considered adherence metrics that use rates of "filled" prescriptions as proxies for "consumed" prescriptions. Appendix I contains a detailed description of the methodology used to calculate these adherence metrics for EQ2. Results for Medication Possession Ratios (MPRs) are presented in Table 8 after applying the aforementioned inclusion-exclusion criteria. There are a few additional limitations of the data that affected the number of participants included in these two metrics, noted as follows. There is one member of the MTM-P group and 19 members of the MTM-NP group with zero chronic conditions, and therefore no recorded adherence, in the pre-intervention period. Likewise, no chronic conditions were identified for 59 recipients in the MTM-NP group even though they had prescription claims reported in the intervention period. Additionally, 16 recipients in the MTM-P group and 165 in the MTM-NP group had no prescription drug claims reported during the intervention period. These persons are still included in the demographic breakdowns summarized under EQ5.

- Adherence as measured by MPRs was very high overall in both study periods.
- Mean MPRs ranged from .91 to .94 and were similar for each study group across study periods.

Table 8. Summary statistics on MPRs for the MTM-P and MTM-NP groups by study period, Florida MTM program evaluation, June 1, 2014 - December 31, 2015.

Study Group	Study Period	Num. Recips.	Mean MPR	Std. Dev.	Min.	Max.	Mean 95% LCL	Mean 95% UCL
MTM-P	SP-PRI	133	0.91	0.07	0.65	1.00	0.89	0.92
MTM-NP	SP-PRI	2,859	0.91	0.08	0.40	1.00	0.91	0.91
Combined	SP-PRI	2,992	0.91	0.08	0.40	1.00	0.91	0.91
MTM-P	SP-INT	118	0.94	0.07	0.70	1.00	0.93	0.95
MTM-NP	SP-INT	2,654	0.92	0.08	0.38	1.00	0.92	0.92
Combined	SP-INT	2,772	0.92	0.08	0.38	1.00	0.92	0.92
MTM-P	Combined	251	0.92	0.07	0.65	1.00	0.91	0.93
MTM-NP	Combined	5,513	0.91	0.08	0.38	1.00	0.91	0.92
Combined	Combined	5,764	0.91	0.08	0.38	1.00	0.91	0.92

Results for the Proportion of Days Covered are presented in Table 9. The same limitations as detailed in the MPR section above hold for these PDC results.

- Adherence as measured by PDCs was very high overall in both study periods.
- Mean PDCs ranged from .90 to .93 and were similar for each study group across study periods.
- While the change in the MTM-P group's mean PDC between the intervention and pre-intervention period (.03) is greater than the change in the MTM-NP group (.01), this difference is not statistically significant after controlling for differences in observation lengths (see Appendix III for the model output).

Table 9. Summary statistics on PDCs for the MTM-P and MTM-NP groups by study period, Florida MTM program evaluation, June 1, 2014 - December 31, 2015.

Study Group	Study Period	Num. Recips.	Mean MPR	Std. Dev.	Min.	Max.	Mean 95% LCL	Mean 95% UCL
MTM-P	SP-PRI	133	0.90	0.08	0.64	1.00	0.88	0.91
MTM-NP	SP-PRI	2,859	0.90	0.09	0.40	1.00	0.90	0.90
Combined	SP-PRI	2,992	0.90	0.09	0.40	1.00	0.90	0.90
MTM-P	SP-INT	118	0.93	0.07	0.69	1.00	0.92	0.95
MTM-NP	SP-INT	2,654	0.91	0.09	0.38	1.00	0.91	0.91
Combined	SP-INT	2,772	0.91	0.08	0.38	1.00	0.91	0.91
MTM-P	Combined	251	0.91	0.07	0.64	1.00	0.91	0.92
MTM-NP	Combined	5,513	0.90	0.09	0.38	1.00	0.90	0.91
Combined	Combined	5,764	0.91	0.09	0.38	1.00	0.90	0.91

EQ3: How many and what type of recommendations for medication change are made by the UF COP staff for the MTM participants?

EQ4: How many recommendations for medication change are adopted in the intervention period by the MTM participants and their providers?

EQ3 and EQ4 results are presented simultaneously. Issues and resolutions are combined into one table for clarity. Table 10 presents counts of pharmacists' medication change recommendations and their respective resolution rates. There are 76 unique participants represented in the table. The reader should note that some of the counts in Tables 10 and 13 differ from analogous measures in the quarterly reports because UF COP pharmacists removed some false positives in the data initially flagged by the software but that were not communicated to the FSU evaluation team on the backend.

- The overall resolution rate (45.6%) is consistent with the norm for physicians' acceptance of pharmacists' medication change recommendations in MTM programs (Doucette, McDonough, Klepser, & McCarthy, 2005; Pellegrino, Martin, Tilton, & Touchette, 2009).
- 70% of drug-drug interactions were resolved.

Table 10. Number of recommendations for medication change and adopted resolutions for MTM intervention participants, Florida MTM program evaluation, June 1, 2015 - May 31, 2016.

Medication Issue	Count of Identified Issues				Count of Resolutions				Resolution Rate
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Drug-Drug Level 1 (Severe)	1	1	0	1	1	0	0	0	33.3%
Drug-Drug Level 2 (Major)	4	2	0	1	4	2	0	0	85.7%
Duplicate Therapy	2	0	0	0	2	0	0	0	100%
Duplicate Therapy (GSDD)	0	4	2	2	0	3	2	1	75.0%
Excessive Number of Physicians	2	0	0	0	2	0	0	0	100%
Excessive Use - Excessive Pill Burden	2	0	0	0	0	0	0	0	0%
Excessive Use of Short Acting Beta-Agonist with Suboptimal Asthma Control (SAC)	3	0	0	0	3	0	0	0	100%
Excessive Use of Short Acting Bronchodilator in COPD	4	0	0	0	3	0	0	0	75.0%
Inappropriate Dosage - Excessive Dosage	1	0	0	0	0	0	0	0	0%
Inappropriate Dosage - Excessive Dosage (GSDD)	0	0	0	1	0	0	0	0	0%
Inappropriate Dosage - Insufficient Dosage	1	0	0	0	1	0	0	0	100%
Inappropriate or Suboptimal Use - Suboptimal Beta-Blocker in Heart Failure	5	0	0	0	1	0	0	0	20.0%
Lack of Efficacy	2	0	0	0	2	0	0	0	100%
Lack of Therapy - Absence of Controller Therapy (ACT) in Asthma	1	0	0	0	0	0	0	0	0%
Lack of Therapy - Absence of Rescue Inhaler in COPD	3	0	0	0	2	0	0	0	66.7%
Lack of Therapy - Diabetic without Statin Therapy	13	0	0	0	2	0	0	0	15.4%
Lack of Therapy - Diabetic without an ACEI or an ARB	5	0	0	0	1	0	0	0	20.0%
Lack of Therapy - Heart Failure without a Beta Blocker	2	0	0	0	2	0	0	0	100%
Lack of Therapy - Heart Failure without an ACEI or an ARB	7	0	0	1	3	0	0	0	37.5%
Lack of Therapy - Lack of Vaccinations	16	1	0	0	1	1	0	0	11.8%
Lack of Therapy - Long-Term Steroid without Antiresorptive Agent	1	0	0	0	0	0	0	0	0%
Lack of Therapy - Osteoporosis without an Antiresorptive Agent	5	0	0	0	0	0	0	0	0%
Lack of Therapy - OTC	1	0	0	0	0	0	0	0	0%

Medication Issue	Count of Identified Issues				Count of Resolutions				Resolution Rate
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Lack of Therapy - Other Indication	7	2	1	0	0	2	2	0	0%
Side Effect	17	0	1	0	13	0	1	0	77.8%
Total	105	10	4	6	43	8	5	1	**45.6%**

Table 11 presents counts and resolution rates of medication adherence issues. There are 16 unique participants represented in the table.

- There was a very high resolution rate for adherence issues (97.4% overall).

Table 11. Number of medication adherence issues and resolutions for MTM intervention participants, Florida MTM program evaluation, June 1, 2015 - May 31, 2016.

Medication Issue	Count of Identified Issues				Count of Resolutions				Resolution Rate
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Adherence Financial Barriers	5	0	0	0	5	0	0	0	100%
Adherence Other	13	11	0	1	12	11	0	1	96.0%
Adherence Perceived Lack of Benefit/Health Beliefs	5	0	0	0	5	0	0	0	100%
Adherence Side Effect(s)	3	0	0	0	3	0	0	0	100%
Total	26	11	0	1	25	11	0	1	**97.4%**

The qualitative analysis indicated that some CMRs focused on lifestyle issues. Identified lifestyle issues and resolution rates are presented in Table 12. There are 42 unique participants represented in the table.

- The most frequent lifestyle issue by far was tobacco use. 32 of the 158 MTM-P (20.3%) reported tobacco use during their CMR. Only 1 of these cases was resolved during the intervention period.
- The resolution rate for all lifestyle issues of 8.3% is fairly low; however, these issues were not supposed to be the main focus of the MTM, so it is unclear how often resolutions were even attempted for these lifestyle issues.

Table 12. Number of lifestyle issues identified and resolved for MTM intervention participants, Florida MTM program evaluation, June 1, 2015 - May 31, 2016.

Lifestyle Issue	Count of Identified Issues				Count of Resolutions				Resolu-tion Rate
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Lifestyle Issue - Excessive Alcohol Use	1	0	0	0	0	0	0	0	0%
Lifestyle Issue - Excessive Caffeine Use	7	0	0	0	0	0	0	0	0%
Lifestyle Issue - Illicit Drug Use	4	0	0	0	1	0	0	0	25.0%
Lifestyle Issue - Inappropriate Medication Administration/Technique	3	0	0	0	2	0	0	0	66.7%
Lifestyle Issue - Lack of Exercise	1	0	0	0	0	0	0	0	0%
Lifestyle Issue - Tobacco Use	32	0	0	0	1	0	0	0	3.1%
Total	48	0	0	0	4	0	0	0	**8.3%**

Table 13 presents the completed CMR activities for the MTM-P.

- UF COP sent all MTM-Ps a Medication Action Plan.
- 111 unique MTM-Ps (70%) received some type of direct counseling on medication related concerns.

Table 13. CMR activities completed for MTM intervention participants, Florida MTM program evaluation, June 1, 2015 - May 31, 2016.

CMR Activity	Number of Participants	Percentage of Participants
Counseled on Diet/Exercise	19	12.0%
Counseled on Lifestyle Modifications	11	7.0%
Counseled on Medication (General, side effects, indication, etc.)	98	62.0%
Counseled on Medication Adherence/Compliance	34	21.5%
Counseled on Medication Administration/Technique	20	12.7%
Counseled on Preventative Screenings/Vaccinations	32	20.3%
Counseled on Smoking Cessation	37	23.4%
Educated on Asthma/COPD	19	12.0%
Educated on Coverage Gap	2	1.3%
Educated on Diabetes	19	12.0%
Educated on Disease State (Other)	16	10.1%
Educated on Dyslipidemia	6	3.8%
Educated on GERD	2	1.3%
Educated on Heart Failure	9	5.7%
Educated on Hypertension	37	23.4%
Medication Action Plan (MAP) Mailed to Member	158	100%

EQ5: What are the demographic characteristics of MTM participants compared to all other eligible waiver recipients, and are there any significant differences?

Descriptive information on the demographic characteristics of the intervention group (MTM-P) and comparison group (MTM-NP) is presented in the following tables. Frequencies and proportions are presented for the MTM-P and MTM-NP groups by each of the demographic variables. Chi-square tests were conducted to highlight any significant demographic differences between the MTM-P and MTM-NP study groups, and Bonferroni adjustments[2] were applied for multiple chi-square tests within EQ5 to determine the required p-value to achieve significance. There were 5 chi-square tests performed, and a p-value less than 0.01 is employed to establish statistical significance. Each demographic measure is presented in its own table, with chi-square results posted below the table.

Interpretation of Descriptive Tables for EQ5

Table 14 presents the age group distributions for the MTM-P and MTM-NP study groups. Age groups were divided as: under 21, 21-40, 41-50, 51-55, 56-60, 61-65, and over 65. Chi-square test results show significant differences in the distribution of age groups between the two study groups.

- Both study groups had very few patients in the under 21 and over 65 groups.
- For the MTM-P group, 41% of all patients were in the 56-60 age group, while this age group accounted for only 20.4% of the MTM-NP group. In contrast, the largest age group for MTM-NP was the 61-65 age group, which accounted for 32.3% of the MTM-NP study group, compared with 12.7% of the MTM-P study group.

[2] Five chi-square tests were conducted within EQ5, resulting in the decision to apply a conservative Bonferroni adjustment to the traditional .05 alpha level (i.e., .05/5=.01). This adjustment corrects for the increase in the likelihood of committing a Type I error when multiple hypotheses are tested.

Table 14. Frequency and proportion of patients categorized by their age on the last day of the pre-intervention study period for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Age Group	MTM-P	MTM-NP	Total
<21	1	47	48
(%)	(0.7)	(1.6)	(1.6)
21-40	8	405	413
(%)	(6.0)	(14.1)	(13.7)
41-50	26	404	430
(%)	(19.4)	(14.0)	(14.3)
51-55	27	472	499
(%)	(20.1)	(16.4)	(16.6)
56-60	55	587	642
(%)	(41.0)	(20.4)	(21.3)
61-65	17	929	946
(%)	(12.7)	(32.3)	(31.4)
Over 65	0	34	34
(%)	(0.0)	(1.2)	(1.1)
Total	134	2,878	3,012
(%)	(100)	(100)	(100)

Note: Chi-square difference test results show evidence that age group distribution varies by study group (Pearson Chi-square 53.3; p=.0001).

Table 15 presents the race distributions for the MTM-P and MTM-NP study groups. Race was categorized into the following groups: black, Hispanic, white, and other. Using the adjusted p-value of 0.01, chi-square test results do not show significant differences in the distribution of race between the two study groups.

- The white group was the largest at 53.7% for the MTM-P study group and 44.1% for the MTM-NP study group.
- The second largest group for the MTM-P study group with “other” at 20.9%, though “other” only comprised 17.8% for the MTM-NP group.
- The second largest group for MTM-NP was black at 20.3%, compared with 16.4% for the MTM-P study group.
- The Hispanic group was the smallest at 9.0% for the MTM-P group. In contrast, Hispanics comprised 17.9% of the MTM-NP group.

Table 15. Frequency and proportion of patients categorized by race for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Race	MTM-P	MTM-NP	Total
Black	22	583	605
(%)	(16.4)	(20.3)	(20.1)
Hispanic	12	516	528
(%)	(9.0)	(17.9)	(17.5)
White	72	1,268	1,340
(%)	(53.7)	(44.1)	(44.5)
Other	28	511	539
(%)	(20.9)	(17.8)	(17.9)
Total	134	2,878	3,012
(%)	(100)	(100)	(100)

Note: Chi-square difference test results show evidence that the distribution of race does not vary by study group (Pearson Chi-square 10.2; p=.0168).

Table 16 presents the ethnicity distributions for the MTM-P and MTM-NP study groups. Ethnicity was categorized into two groups: Hispanic and non-Hispanic. Using the adjusted p-value of 0.01, chi-square test results show significant differences in the distribution of ethnicity between the two study groups.

- In contrast to the distribution of race, which shows 12 MTM-P individuals identify as Hispanic, there are 14 individuals who identify as Hispanic for the ethnicity reporting. This discrepancy is due to the fact that "Hispanic" is considered an ethnicity, even though it is often included in racial categories, and some Hispanics do consider this heritage a part of their racial identity. For example, an individual may list their race as white and their ethnicity as Hispanic, instead of reporting their race as Hispanic.
- The MTM-P group had 10.4% of patients identifying as Hispanic, compared with 20.3% of the MTM-NP study group.

Table 16. Frequency and proportion of patients categorized by ethnicity for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Ethnicity	MTM-P	MTM-NP	Total
Hispanic	14	583	597
(%)	(10.4)	(20.3)	(19.8)
Non-Hispanic	120	2,295	2,415
(%)	(89.6)	(79.7)	(80.2)
Total	134	2,878	3,012
(%)	(100)	(100)	(100)

Note: Chi-square difference test results show evidence that ethnic group distribution varies by study group (Pearson Chi-square 7.8; p=.0054).

Table 17 presents the gender distributions for the MTM-P and MTM-NP study groups. Gender was categorized as female, male, or unknown. Chi-square test results do not show significant differences in gender distribution between the two study groups.

- The proportion of female patients was greater than males for both the MTM-P (52.2%) and MTM-NP (50.8%) study groups.
- There was only one patient with gender listed as "unknown" in the MTM-NP study group and none in the MTM-P study group.

Table 17. Frequency and proportion of patients categorized by gender for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016.

Gender	MTM-P	MTM-NP	Total
Female	70	1,461	1,531
(%)	(52.2)	(50.8)	(50.8)
Male	64	1,416	1,480
(%)	(47.8)	(49.2)	(49.1)
Unknown	0	1	1
(%)	(0.0)	(0.03)	(0.03)
Total	134	2,878	3,012
(%)	(100)	(100)	(100)

Note: Chi-square difference test results show no evidence that gender distribution varies by study group (Pearson Chi-square 0.16; p=.9253).

Table 18 presents the primary language distributions for the MTM-P and MTM-NP study groups. Primary language was categorized into the following groups: English, Spanish, and "other" languages. Using the adjusted p-value significance level of 0.01, chi-square difference test results show evidence that primary language distribution varies between the two study groups.

- The English group was the largest at 97.0% for the MTM-P study group and 87.5% for the MTM-NP study group, followed by the Spanish group at 3.0% and 11.6% and the other language group at 0% and 0.9% in the MTM-P and MTM-NP groups, respectively.

Table 18. Frequency and proportion of patients categorized by primary language for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - May 31, 2016

Language	MTM-P	MTM-NP	Total
English	130	2,518	2,648
(%)	(97.0)	(87.5)	(87.9)
Spanish	4	334	338
(%)	(3.0)	(11.6)	(11.2)
Other	0	26	26
(%)	(0.0)	(0.9)	(0.9)
Total	134	2,878	3,012
(%)	(100)	(100)	(100)

Note: Chi-square difference test results show evidence that primary language distribution varies by study group (Pearson Chi-square 11.01; p=.0041).

Table 19 presents findings for the mean number of chronic conditions in the MTM-P and MTM-NP population study groups based on the conditions tracked by University of California San Diego (UCSD) School of Medicine's MRX system. The number of individuals differs by study period because some recipients were missing pharmacy claims in the intervention period.

- The mean number of chronic conditions was slightly higher for the MTM-P study group in both study periods, though this difference was not statistically significant for either period.

Table 19. Summary statistics and significance tests for the mean number of chronic conditions tracked by UCSD's MRX system for the MTM-P and MTM-NP study groups, Florida MTM program evaluation, June 1, 2014 - December 31, 2015.

Study Group	Study Period	Num. Recips.	Mean Number of Chronic Conditions	Minimum	Maximum	Mean 95% LCL	Mean 95% UCL	T-test of CCC* mean MTM-P vs. MTM-NP	
								T	Pr<|t|
MTM-P	SP-PRI	134	6.28	0	14	5.76	6.81		
MTM-NP	SP-PRI	2,878	5.77	0	17	5.66	5.88	-1.88	0.06
MTM-P	SP-INT	118	5.08	1	11	4.60	5.57		
MTM-NP	SP-INT	2,713	4.93	0	17	4.82	5.04	-0.57	0.57

*Chronic Condition Count

Quantitative Evaluation Discussion

The current literature on MTM suggests that many patients receiving MTM services see

improved health outcomes that include: 1) better medication adherence, 2) reduced exposure to potential drug-drug or drug-disease interactions, and 3) reduced instances of over or under medication. However, the majority of published studies evaluating MTM programs were conducted on populations of working age adults covered by private insurance through their employer or within the covered population of private insurance companies providing Medicare Part D coverage to an elderly Medicare population. Typically, these published evaluations included a large number of patients who received MTM counseling and were followed for at least one year.

The object of this evaluation was to examine the effectiveness of an MTM program in the context of a publicly funded Medicaid population of mostly working-age adults who were not working due to the impact their disease or condition has on their ability to function in the workplace. All of the Medicaid recipients in this population have received a disability determination from the Social Security Administration.

The results of previous evaluations of the Florida Medicaid MTM program for Cohorts 1 through 4 found no statistically significant improvements in the intervention groups when contrasted with their respective comparison groups. Given this consistent lack of evidence for any intervention effect, combined with far-reaching concerns about the internal validity of the study, the quantitative component was considerably scaled back for the evaluation of Cohort 5 (and future Cohorts 6 and 7) in favor of expanding the qualitative component.

Accordingly, the results of the pared down quantitative analysis from the current evaluation mirrored the results from analogous analyses completed for evaluation of the previous four cohorts. Specifically, medication adherence, as measured via MPR and PDC metrics, was quite high and quite stable across both study groups and time periods. The discussion will focus on MPRs since PDC scores were not assessed in the previous evaluations.

- Cohort 5 MPRs hovered just above .90 for both groups and time periods, averaging .91 for each group in the pre-intervention period and .94 for MTM-Ps versus .92 for MTM-NPs in the intervention period. This difference is not statistically significant after applying appropriate controls for shorter observation lengths.
- Similarly, Cohort 4 MPRs averaged .89 for both groups in the pre-intervention period and .88 for both groups in the intervention period.

This proxy measure of adherence is practically at ceiling for MTM-P and MTM-NP prior to implementation of the intervention. The results from EQ1 analysis also suggests a similar ceiling effect, with 96% of included MTM-P demonstrating 100% adherence based on UF COP's methodology. Moreover, direct measures of adherence via Morisky questionnaires from past evaluations indicated MTM-Ps entered into the intervention with very high levels of adherence (Cohort 4 averaged .59 points on the 0-8 additive scale, with 0 indicating ideal adherence.)

Nationally, MTM programs often report resolution rates around 40 percent. Therefore, the overall resolution rate of 45.6% for Cohort 5 medication change recommendations and issues is within the normal bounds, although toward the upper bound, of typical MTM programs. This is the highest resolution rate reported for the five completed MTM interventions. Previous cohorts' resolution rates were 40.4%, 32.7%, 25.9% and 40.5% for Cohorts 1 through 4, respectively. Additionally, the reported resolution rate for medication adherence issues of 97.4% represents one area of programmatic success. Although no direct comparison group is available for the purpose of gauging UF COP MTM services, UF COP staff identified many problems within Cohort 5's intervention group:

- 10 clinically significant Level 1 or 2 drug interaction problems were identified; 7 were resolved.
- 21 instances where pill burden could be decreased by use of combination therapy, removal of duplicate therapies, or excessive use of therapies were identified; 14 were resolved.
- 72 instances of a gap in therapy, insufficient dosage, insufficient duration of therapy, or a lack of therapy were identified; 18 were resolved.
- 17 instances of unwanted side effects were identified; 13 were resolved.
- 125 total problems were identified among Cohort 5 MTM-Ps; 57 (45.6%) were resolved.

In addition to medication issues, UF COP staff identified several lifestyle issues that likely have a negative impact on MTM-Ps' overall health and well-being, the most common of which include tobacco use (32 instances), illicit drug use (4 instances), and excessive caffeine intake (7 instances). Few of these lifestyle issues were resolved (2 instances out of those previously listed). While these issues were not the main focus of the intervention, qualitative analysis indicated that some CMRs focused on these lifestyle issues.

Quantitative Evaluation Limitations

This study used a quasi-experimental design to examine the relationship between providing telephone-based MTM program counseling to an intervention group as compared with a non-equivalent

comparison group that received no programmatic medication counseling service. The gold standard research design for program effectiveness using random assignment to the intervention and control group was not possible because Medicaid recipients were not required to participate in the intervention. Moreover, even if the study met the experimental gold standard, pre-intervention adherence was practically at ceiling, leaving little ability to discern any intervention effect on levels of medication adherence.

Quantitative Evaluation Recommendations and Next Steps

The following recommendations emerged from the quantitative evaluation of the MTM.

1) The quantitative evaluation team recommends that UF COP target those with lower adherence scores for recruitment into the MTM program intervention group. Currently, most MTM-Ps are at, or at least near, ceiling for adherence scores in the pre-intervention period. Detecting a subsequent treatment effect on adherence is impracticable if there is no room for improvement in adherence. Therefore, if the Agency agrees to provide the pre-intervention pharmacy claims in the spring before the intervention, the evaluation team is offering to calculate MPR and PDC scores for all recipients in the original query for this purpose. This action could be implemented for Cohort 7. Targeting those with lower levels of adherence would provide two benefits; first, there may be a treatment effect for those who manifest lower levels of adherence prior to receiving MTM services; second, and more importantly, UF COP will reach those most in need of MTM services.
2) Given the continued lower levels of participation in the MTM program for Hispanic recipients, the evaluation team recommends that UF COP uses a stratified sampling technique in an attempt to recruit a representative proportion of Hispanic recipients into the intervention group.

The quantitative team encountered several obstacles while working with the UF COP data; hence, the following "next steps" relate to resolving these data issues. The evaluation team hopes to work more closely with UF COP in the future to facilitate better understanding of UF COP's data processes and software limitations, especially since UF COP implemented a new, unexpected data collection process in Cohort 5.

- There are potential discrepancies in identified adherence issues between the Medications and the Drug Therapy Problem (DTP) spreadsheets. There are 16 unique participants with 38 identified adherence issues in the DTP data, while only 6

participants manifested adherence issues in the Medications data. The quantitative evaluation team would like to work with UF COP to better understand these data sources and the causes of these discrepancies. Specifically, the evaluation team would like to know how UF COP identifies adherence issues in one report versus the other.

- The quantitative evaluation team asks that the UF COP data manager(s) insert a flag for false positives in the DTP report and requests further explanation for how pharmacists identify these false positives.
- The quantitative evaluation team asks that the UF COP data manager(s) add the date of the adherence assessment to the Medications report so that they can calculate adherence rates and subsequent changes in adherence before and after the CMR.

Qualitative Evaluation Findings

The evaluation team conducted a thematic analysis of transcripts of a selection of 33 CMR calls and a random selection of the quality assurance questions during 47 of the CMR calls and 37 of the 30 to 60-day follow-up calls. The analysis focused on components of the CMR (EQ9), valuable components of the MTM program (EQ6), CMR assistance to participants (EQ7), and rating of overall care (EQ8). As EQ9 contextualizes the findings of the other EQs, it is presented first. The findings are presented in this section.

Data regarding demographic characteristics were available for 33 participants who received CMR calls. These data are listed below in Table 20.

Table 20. Demographics of qualitative sample of the CMR calls.

Demographic Variable	Sample Composition
Gender	48.5% Female (n=16) 51.5% Male (n=17)
Race/Ethnicity	15.2% Black (n=5) 9.1% Hispanic (n=3) 15.2% Not identified (n=5) 6.1% Other (n=2) 54.5% White (n=18)
Age	Mean=52.1 years (SD=9.8)
Primary Language English	97% (n=32)

EQ9: What are the components of the CMR provided by the UF COP pharmacists? (e.g., How is the CMR implemented?)

Before examining the CMR components in depth, it is important to understand the CMR more broadly. This first section examines the context in which the calls occur. Subsequent sections examine the CMR delivery and the skills of the pharmacist.

Context

The comprehensive medication review (CMR) consists of a pharmacist's assessment of participant medications including prescription drugs, over the counter (OTC) products and herbal supplements, which is then used to compile an overall list to provide information and education on potential drug therapy problems as well as overall general information. This information is collected through a systematic procedure guided by a script wherein pharmacists contact participants via telephone and review medications to obtain an updated overall list. The review is guided by a medication list provided by a participant or the pharmacist.

Prior to the phone call, the pharmacist has access to a participant's profile via their electronic patient chart. This chart includes the participant's name, gender, date of birth, preferred language and alternative language, if applicable. Insurance plan and contact information are also included in the patient chart as well as participant preferred pharmacy and provider name with contact information.

Per the CMR script, the pharmacist asks questions to obtain an updated medication list from the participant. These questions begin with a confirmation of the participant's identity to ensure protection and privacy of sensitive information. The pharmacist then begins the medication review, which includes questions about prescription medications, OTC medications and herbal supplements as well as any other complimentary medications. The pharmacist then asks specific questions related to the name of the medication, dose, strength directions, purpose, side effects, adherence and prescriber information. If there are any interactions between medications identified during the call, the pharmacist addresses these concerns with the participant by probing more. The pharmacist provides the participant with any necessary information related to these concerns. Lifestyle questions and the participant's social history are obtained after the completion of the medication review. These questions include information about the participant's use of alcohol, tobacco and caffeine as well as exercise patterns, diet and living arrangements. The final portion of the CMR consists of reviewing identified allergies, vaccination history and laboratory information.

The CMR script was followed by most of the pharmacists, although the order in which these questions were asked sometimes varied. About half of the CMRs included the lifestyle questions asked prior to the actual medication review and the other half occurred in the reverse order. However, all CMRs began with the pharmacist confirming the participants identify prior to eliciting more information to complete the review.

UF COP pharmacists telephoned participants to conduct CMRs. Sometimes the calls were scheduled ahead of time by a UF COP staff member, while other times the calls were initiated by the pharmacist and the CMR was conducted at the time of the call. There were several things worthy of note in the sample of CMR calls that will be described in more detail later in this section. In general, there were few problems with sound quality and phone connection. To understand the MTM program and the CMRs, acknowledging the role and behavior of the participant is important. In some cases, participants displayed resistance while others were exceptionally talkative. This level of engagement and information impacted how the CMRs were conducted as well as the length of the call. It was not uncommon in the calls for there to be confusion and difficulty in understanding between the pharmacist and participants.

Overall Quality of Sound and Phone Connection

The quality of the transcribed phone calls did not negatively impact the CMRs even when the calls were made to participants' cell phones. While there were a few instances of noise in the background (e.g., people talking, television sound) and issues with hearing, there were not pervasive problems and the CMRs were able to be completed successfully.

There were two CMR calls when the call was interrupted due to problems with the phone connection. These "dropped calls" both seemed to be due to participants' use of cell phones. In each case, the pharmacist was successfully able to call and reconnect with the participant. Once reconnected, the CMR continued. It is worthy to note that the sample includes the longer calls, and sound quality and phone connection may have been an issue with shorter calls.

Participant Resistance

While it was not a significant pervasive issue, participant resistance was observed during some of the calls. Some participants displayed passive resistance by answering questions in mostly "yes" or "no" responses and not elaborating or asking any questions of the pharmacists. Sometimes this seemed to be due to a lack of interest and a sense of obligation to participate in the CMR. At times, this type of passive resistance was mitigated by pharmacist engagement (i.e., sharing related personal information,

offering support), but, in general, it seems that participants were either very engaged in the call or minimally interested and demonstrated some resistance.

Sometimes participant discomfort was observed during sensitive questions about drug and alcohol use, and resistance was observed to increase along with this discomfort. It is also important to note that the pharmacists did not consistently inform the participants that their answers to these questions would not affect their insurance coverage.

Talkative Participants

Some participants were quite talkative and shared extensive information about their lives. These individuals quite frequently answered questions—sometimes closed ended questions—and provided many details, some of which were not necessarily relevant to the question the pharmacist asked. Many times the information participants provided was related to their health. Most of the time pharmacists displayed active listening skills in an effort to both listen and to connect the conversation to the participant's health and the CMR.

Some talkative participants were less focused and took the conversation in divergent directions that were not always connected to health care. These participants who talked about topics less related to their health care sometimes appeared reluctant to have the call end.

All pharmacists listened to and accommodated talkative participants. Their strategies and ability to redirect and focus participants varied. When dealing with talkative participants, some pharmacists seemed better able and more effective at shaping the interview in a clinically useful manner.

CMRs were longer when participants were talkative and, in general, participants who were more talkative generally expressed gratitude to the pharmacist for taking the time to listen to them.

Confusion and Difficulty Understanding

Both participants and pharmacists appeared to have difficulties understanding aspects of the conversation at varied points throughout the CMRs. Often this was when pharmacists would ask questions about specific health related issues and the participants clearly had difficulty understanding. This confusion appeared to be related to the pharmacists' use of technical terms or jargon as well as participants' cognitive and educational levels. Some of the participants further acknowledged they had a difficult time understanding things due to health issues (e.g., strokes) or side effects of medication.

Participants' confusion and difficulty understanding was sometimes resolved when pharmacists recognized participant confusion or lack of understanding and asked questions in a different manner. However, in some instances, pharmacists did not appear to detect the participant confusion and simply

continued the CMR, moving on to another question. This was observed especially with one pharmacist who seemed to experience difficulty in perceiving participants' confusion. This led to awkward transitions between topics and sometimes created a disjointed conversation.

Sometimes the pharmacists experienced confusion and had difficulty understanding participants. Often they asked questions or asked participants to explain more. However, sometimes pharmacists did not seek clarification and continued on with the conversation.

While the confusion and difficulty understanding was a regular occurrence, it often was rectified by most pharmacists. However, when it went undetected or unaddressed, the quality of the CMR seemed to be impacted. Participants seemed less likely to engage when there was confusion, and the CMR did not seem as in-depth.

CMR Delivery

Variation existed in how the CMR was delivered depending on the pharmacists as well as the participants. However, there were consistencies across CMRs in how pharmacists gathered information on participants' medicine and lifestyle. Likewise, there were core elements of verifying medication and discussing potential adverse effect and issues related to medication adherence. In each CMR pharmacists gave participants opportunities to ask questions. One area in which there was great discrepancy in how the CMR was delivered was in the use of disclaimers about recording the phone call and confidentiality. These themes are expanded on below.

Gathering Medication Information

At the beginning of each CMR, pharmacists asked participants to gather their bottles of medications or a list of their medications. Since some of these calls were scheduled in advance, some participants already had the bottles or list available. Pharmacists told participants that they had a list of their medications as well. Sometimes pharmacists gave participants the option of reviewing medications from either the participants' list or medication bottles or the pharmacist's list. In either case the CMR began with a systematic review of each of the participant's medications.

Verification of Medications

The central part of the CMR was discussing the medications of the participant. Pharmacists verified each of the medications with the participant including the dosage and how the participant was taking the medication. They also asked about the use of over the counter (OTC) medications. When the medication was taken as prescribed, the conversations about the medication went more quickly. When there were issues with adherence, the pharmacist spoke more in depth about specific medications.

Medication Adherence

Discussions about medication adherence were observed throughout the CMR. Pharmacists asked participants to provide information on dosage and directions for use of each medication reviewed. Specific discussion about medication adherence questions varied among pharmacists and participants. Occasionally, pharmacists would ask the participants if they were able to take the medication as prescribed, in addition to asking about the intended use. Other times, pharmacists would ask the participants to simply provide the directions (i.e. dosage, frequency, intended use) for each medication reviewed. Frequently participants were unsure of the particular reasons they were taking medications; however, this did not appear to significantly deter them from complying with taking the medication. Sometimes there was confusion about the directions and misconceptions about the medication. Rarely did participants ask questions about medication adherence. Pharmacists addressed participants' use of OTC medication in addition to their prescribed medication.

Pharmacists provided additional information about how medication should be taken. For example, they explained when medication needed to be taken with food and medication that should be taken at certain times of the day. Pharmacists sometimes clarified what medications could be taken as needed. They also sometimes provided specific instructions for using certain medications. Participants often did not know complete information about how the medication was to be taken. Some participants even indicated that although they took the medication, they did not understand it fully.

Discussion of Side Effects

As pharmacists discussed individual medications with participants, they frequently asked participants about side effects. However, there were instances where the participant would mention symptoms and ask the pharmacist directly if these symptoms could be related to specific medications. These questions initiated by the participants about side effects occurred at a much lower rate than pharmacist driven discussions about side effects. While most of the focus on side effects were on the more common side effects, pharmacists also reviewed the serious, yet rarer side effects. When pharmacists were discussing serious yet rare side effects, they largely were providing information for what participants should look for as warning signs of the side effects. In addition to identifying side effects, pharmacists also talked with participants about how they could address and manage adverse effects. Throughout the CMRs, including when discussing side effects, pharmacists encouraged participants to talk with their physicians.

Conversations about medication side effects generally occurred during the review of medications, or around the middle of the call. However, discussions about adverse effects were not

limited to just the medication review. These conversations were also observed toward the end of the call and throughout all aspects of the call (i.e. lifestyle questions, QA) as needed.

Lifestyle Question

Pharmacists asked detailed information about participants' lifestyles and if participants engaged in certain activities or had specific health concerns. In almost all of the CMRs, pharmacists asked about nicotine use; exercise and physical activity; diet; caffeine use; alcohol use; drug use; flu and pneumonia shots; high blood pressure; and high cholesterol. Pharmacists also asked participants if they had diabetes, heart disease, osteoporosis, and COPD.

Pharmacists often prefaced the lifestyle questions, especially the ones related to drug and alcohol use, with an explanation that these questions were asked of everyone. These lifestyle questions were typically asked as closed ended questions and pharmacists did not ask participants to elaborate.

Health Education

In most of the calls pharmacists provided some form of basic health education. There was a range of topics covered including smoking cessation, diet, fiber, using stool softeners, hydration, and exercise. The information was tailored to the specific needs and interests of participants. For example, smoking cessation was discussed with participants who indicated that they smoked and were interested in quitting. The health education provided was often interspersed with the lifestyle questions and was part of a conversation of overall health. For example, after asking if a participant smoked, a pharmacist provided concrete information about smoking cessation and addressed the specific concerns and problems the participant was experiencing. The pharmacist provided tips and ideas and problem-solves with the participant. While not all of the health education was in depth, pharmacists often provided information to participants about how to manage and address their health concerns and improve their health.

Advice

The most frequent advice that pharmacists gave to participants was to talk with their physicians. This was frequently in the context of the participant experiencing side effects or continuing to have the health issue the medication was supposed to address. For example, one participant shared not sleeping well despite taking Trazodone before bedtime. The pharmacist suggested that considering the current prescription and that the participant was not sleeping through the night, the physician may be able to increase the dosage. The pharmacist encouraged the participant to discuss this with the physician. In another instance, a participant who had difficulties swallowing was taking whole pills in applesauce. The

pharmacist suggested that some of the pills could be crushed without affecting the efficacy of the medication and then the crushed pills could be mixed into applesauce which could be consumed more easily.

In some cases, participants shared that they had talked to their physician about concerns, yet the problems were not resolved. Pharmacists encouraged participants to talk with their physicians again and sometimes suggested specific strategies of how to do so. One concern that several participants mentioned that was not addressed when talking to physicians was the costs of medication. Pharmacists discussed how participants can talk to their physician about cost concerns and perhaps find an alternative less expensive medication.

Pharmacists provided specific advice related to medication adherence as well as lifestyle and health education, all of which were previously discussed. This advice was tailored to the specific participant and pharmacists often engaged the participants to determine if the pharmacist's suggestions were feasible. Frequently, the advice that pharmacists offered was through problem solving with participants and identifying several potential ideas.

Soliciting Participant Questions

In all of the calls pharmacists asked participants if they had any questions. This was typically asked at the end of the call after the pharmacist completed the CMR, yet occasionally in the middle of the call. There was a wide range of responses to pharmacists' solicitation of questions. Many participants said they did not have any questions for the pharmacist. It was common for participants to follow-up by saying they appreciated the pharmacist and did not have questions because everything was covered. Some asked health related questions or asked clarifying questions about information from the call. Others, frequently those who had been talkative during the call, introduced new topics some of which were only peripherally related to health.

Disclaimers

In many of the calls the pharmacist did not inform the participant that the call was being recorded for training and evaluation purposes. Likewise, pharmacists did not consistently explain that the information participants provided would not impact their insurance and participation was voluntary. In several cases participants indicated that they participated in the CMR because it was required of their insurance; thus, it appears that not all participants understood the voluntary nature of the MTM program. The CMRs were sometimes scheduled in advance by someone other than the UF COP

pharmacist, and it is possible that all of the disclaimers and a detailed description of the CMR was given at an earlier time and the participants did not remember the details.

Quality Assurance Questions

Pharmacists did not consistently ask the quality assurance questions at the end of the CMRs and during the 30 to 60-day follow-up calls. The quality assurance questions at the end of the CMR focused on participants' perceptions of the helpfulness of the appointment as well as if the conversation with the pharmacist clarified any concerns with their medication. The quality assurance questions during the 30 to 60-day follow-up calls focused on participants' thoughts about the medication list the pharmacists sent following the CMR. It was not readily apparent in some instances why the questions were not consistently asked. However, in some instances participants were rushed to get off the phone and in one instance the participant had been emotional and had just finished crying. The 30 to 60-day follow-up calls were consistently short and often lasted only a few minutes.

Pharmacists' Skills

Pharmacists demonstrated using clinical skills throughout their interactions with participants. In the calls pharmacists engaged participants through active listening; normalizing [3] participants' experiences; providing support and encouragement; and having in-depth conversations with participants.

Active listening

Actively listening is a technique of communication where the listener fully concentrates on what is said and provides feedback that there is understanding. There are various strategies used in active listening including paraphrasing what was said; repeating words the participant used; asking questions for clarification or elaboration; and using utterances to show listening still is occurring (e.g., "uh huh," "mhm," "yeah," "okay", "alright"). Pharmacists consistently actively listened to participants. In general, the pharmacists consistently engaged in active listening. However, occasionally there were instances of interrupting or speaking at the same time. While sometimes this was in the context of getting more information, sometimes this was not the case.

Questions

Pharmacists used various types of question to solicit information from participants as well as to ensure there was understanding between the pharmacist and participant. Sometimes they used open

[3] Normalizing is the process of helping a person realize they are not abnormal for having an experience.

ended questions (those which cannot be answered with yes or no) and other times they used closed ended questions (those which are answered with a yes or no). When the open ended questions were used, participants generally provided more information. Sometimes pharmacists used force choice questions, which provided the answers from which participants could select. Participant confusion was more likely when there were forced choice questions and less information was received by the pharmacists. The same appeared true when pharmacists used suppositional questions, which have an element of assumed knowledge within them. Participants rarely corrected the pharmacists when they asked suppositional questions, although it was clear that sometimes there was confusion and misunderstanding.

Related to the types of questions pharmacists asked was the way in which pharmacists followed up on the information participants provided. In many instances there was a lack of probing for reasons behind participants' answers. For example, participants would say that they were no longer taking a medication and pharmacists would not ask for more details about why they discontinued taking it. Due to the prevalence of poverty and financial hardship in the Medicaid population, it is possible that a lack of financial resources could have been an issue for some MTM program participants. However, this was not always explored. Likewise, with some of the lifestyle questions, pharmacists did not necessarily probe for additional information. There appeared to be some missed opportunities for health education and providing information to participants.

Normalizing

Pharmacists normalized both the CMR process and participants' responses. Pharmacists normalized the CMR process, especially the sensitive topics of the lifestyle questions (e.g., suicide, depression) by indicating that they ask the same questions to everyone and acknowledging that certain topics can be difficult to discuss. For example, this was stressed when asking about drinking alcohol and using drugs.

Pharmacists also normalized participants' responses and experiences. Participants appeared to connect to pharmacists who either normalized experiences or stated that they themselves have experienced something similar. This normalization sometimes took the form of pharmacists sharing personal information in response to something that a participant shared. Examples include sharing a like or dislike of certain types of food; liking the taste of gummy vitamins; liking the mountains; and similar beliefs about the weather. Sharing personal information and the normalization process seemed to assist in building rapport.

Support and Encouragement

Throughout the CMR calls pharmacists consistently provided support and encouragement. Pharmacists were empathetic when participants disclosed health problems and hardships in their lives. Routinely, pharmacists acknowledged how challenging the participant's circumstances were and sometimes the perceived injustices. Participants frequently shared the burden of the cost of health care, especially certain types of medication. Pharmacists supported participants through listening and empathizing with participants.

Pharmacists encouraged and praised participants who were effectively managing their health. Participants regularly shared things that they were doing that worked well for them. The typical response for this was praise and encouragement. When participants were trying to make changes in their behavior to become healthier, pharmacists were encouraging. Pharmacists recognized interest and commitment to being healthier and encouraged it even when it was only in the most initial stages of change. They served as cheerleaders for the participants who were wanting to change and emphasized the positive things they were doing or even planning to do to improve their health.

In-depth Conversations

Most discussions about specific medications followed a standard format and there was not a lot of detailed information. However, when there appeared to be a medication contra-indication, interaction, or concerning side effect; it was common for the pharmacists to engage in a more in-depth conversation.

In addition to in-depth conversations about medication, pharmacists and participants also talked about lifestyle and health more broadly. This typically happened with more talkative participants who more readily shared details about their lives. It also happened more frequently when participants had specific concerns such as issues with being able to afford health care and circumstances that impacted their health such as transportation problems.

EQ6: What do participants perceive to be the most valuable components of the MTM program?

In their responses to the quality assurance questions, participants shared their perceptions of the valuable components of the MTM program. Participants clearly valued learning about medication and having the opportunity to talk with a caring pharmacist. During the 30 to 60-day follow-up call, participants were asked about the receipt and helpfulness of the medication list that was mailed to

them after the CMR. The medication list was not consistently received in the mail, but those who did receive it tended to appreciate it and rated it favorably.

Learning about Medication

Participants shared that the MTM program provided an opportunity for them to learn about their medication. They stressed the program increased their knowledge about medication. When asked if the call clarified any concerns with medication, one participant replied,

> "Yeah. Sure did. What I'm taking and, you know, you talking to me about it and everything, and you see, it feels a lot better. You know, I mean, I can read the paperwork. Sometimes all these words, I, I can't read all these words 'cause I don't know what they mean all the time."

The participant then continued to describe how the CMR had helped, "You know, it makes me feel a lot better. 'Cause now I know, you know, what to take and this is what this is for and this is what that's for and everything." Participants regularly described learning about their medication and how it should be taken.

Caring Pharmacist

Pharmacists clearly demonstrated warmth toward participants through their interactions during the CMR. They used empathetic statements. As described above, pharmacists would often patiently listen as participants shared their experiences about hardships and challenges in their lives, some of which were only peripherally related to their health care. Participants recognized the pharmacist's concern in their responses to the quality assurance questions. Comments from participants about appreciating the pharmacist's caring were common. The words "care" and "caring" were liberally used by participants as they discussed the value of the CMR.

Medication List

During the 30 to 60-day follow-up calls, 13 of the 36 participants stated that they did not receive the medication list in the mail. Thus, over a third of participants did not receive the medication list. In a few instances participants indicated that their address had changed or when the pharmacist confirmed the address, there was an error. In most cases, there was not a clear reason why the participant had not received the mail. Participants would just indicate they did not receive it, as this participant explained, "Yeah, I was kinda looking for it, yea, but I never did get it." Several people were unclear if they had received the medication list in the mail. Most of the participants who had not received the medication list in the mail said they would like another list mailed to them when the pharmacist offered to send one.

Nearly two-thirds or 15 of the 24 participants who received the medication list reported it was helpful. However, few of the participants elaborated on what was helpful about the medication list. One participant stated “It’s good for my records, absolutely.” Another patient said the list would be “handy” to have when going to the doctors.

EQ7: How do participants perceive that the CMR assists them? (e.g., How does the CMR impact participants' ability to understand medications, take a more active part in their care, and understand the questions to ask their doctor or when to contact their doctor?)

The quality assurance questions were closed ended and did not ask for participants to elaborate on how the CMR assisted them. However, participants indicated that sometimes the CMR assisted them by increasing their understanding of their medication; increasing their knowledge about medication and health; and positively impacting their health.

Understanding Medication

As mentioned previously, participants sometimes did not fully understand their medication. During their responses to the quality assurance questions, participants shared that they had a better understanding of their medications due to the CMR. It was not uncommon for participants to not know what medications were for and to have only the most basic understanding of their medications. The CMR provided information to participants that cleared up misconceptions and confusion about their medications. Participants acknowledged that they understood their medication better due to the CMR. Several participants were emphatic that the CMR helped them understand their medications. Others were less so, yet still mentioned that their understanding of their medications improved.

Knowledge Increased

Participants frequently mentioned learning something when they were asked to assess the call during the quality assurance question. Sometimes it was very specific and related to a specific medication. It is worthy to note that some of what was learned may decrease the chances of duplication or overtreatment because of the participants’ increase in knowledge. Other participants specifically mentioned gaining knowledge about something related to health education. Sometimes participants spoke more broadly about the call impacting their knowledge. Thus, even when there were not any concerns with the medication, participants explained they gained knowledge through their conversation with the pharmacist.

Increased Confidence and Self-Efficacy Surrounding Health Care

Several participants shared that the CMR gave them more confidence in their understanding of their health care. For some participants, the CMR provided a sense of security. After talking to the pharmacists, participants' responses seemed to indicate they felt more confident in their knowledge and understanding of medication. This sense of confidence was related to participants who indicated that with the information the pharmacist provided them they felt better prepared to talk with their physicians. This increased sense of self-efficacy was noticeable in the responses of participants who described feeling better equipped to manage their health care and advocate for themselves. A few participants mentioned that the medication list helped them feel more in control and knowledgeable about their health.

EQ8: How do participants rate the overall care they experienced in the MTM program?

In the quality assurance questions at the end of the CMR calls, 30 of the 47 participants responded positively when asked if the call was helpful. While many simply said that yes, the call was helpful, some really emphasized their positive response.

As previously mentioned, the participants perceived the MTM program as positively impacting their health care and participants mentioned they enjoyed talking with the pharmacists. In several calls after the quality assurance questions were asked, participants continued talking with the pharmacists, suggesting that they had connected with the pharmacist during the call. In several of the 30 to 60-day follow-up calls, participants stressed how they appreciated the CMR.

Calls Not Helpful

Only three of the participants answered that the calls were not helpful. In each of these calls the participants stressed that they were familiar with their medications. Each of the CMR calls where participants answered that the calls were not helpful was with a participant who was already highly informed about their medication.

Neutral and Vague Responses

In four instances participants provided vague or neutral responses to the question about the helpfulness of the call. Some were from participants who did not know how to assess the call. In some instances, the participant acknowledges ongoing health problems that may contribute to understanding and being able to fully benefit from the information provided in the CMR. Several participants seemed to believe the call was about their insurance and could ultimately help in the long run. Even in the cases

where participants were vague and did not affirm that it was helpful, they saw value and utility in the CMR.

Qualitative Evaluation Discussion

This evaluation is a thematic analysis of transcripts of audio files of the CMR calls between UF COP pharmacists and MTM program participants. Thus, it is an examination of the intervention that allows for a deeper understanding of the context of the CMRs, the CMR delivery, and the pharmacists' skills. In addition to describing the components of the CMR, this evaluation demonstrates that participants value components of MTM programs including learning about medications, caring pharmacists and medication lists. Participants indicate that the CMR assists them in various ways, specifically increasing understanding of medication, knowledge about health care, and confidence and self-efficacy about their health care. Overall, participants overwhelmingly rated the MTM program favorably and indicated it was helpful. The few participants who reported the program was not helpful for understanding their medications said they previously felt well-informed and had no need for further knowledge.

Summary of Qualitative Evaluation by Research Question

EQ6: What do participants perceive to be the most valuable components of the MTM program?

Participants indicated they valued the MTM program. Specifically, participants appreciated having the opportunity to learn about their medications. Participants stressed the value of talking with caring pharmacists who listened. Additionally, the participants found the medication list that pharmacists sent them to be helpful.

EQ7: How do participants perceive that the CMR assists them? (e.g., How does the CMR impact participants' ability to understand medications, take a more active part in their care, and understand the questions to ask their doctor or when to contact their doctor?)

There are three ways that participants described the CMR as assisting them: 1) understanding medication, 2) increasing knowledge, and 3) increasing confidence and self-efficacy in health care.

During their responses to the quality assurance questions, participants shared that they had a better understanding of their medications due to the CMR. Participants also mentioned becoming more knowledgeable about their health. Some shared what they learned about their health through the health education provided by pharmacists. Several participants indicated the CMR helped them feel

more confident in their knowledge and understanding of medication. Some participants described feeling better equipped to manage their health care and advocate for themselves.

EQ8: How do participants rate the overall care they experienced in the MTM program?

Overall, the vast majority of participants felt the MTM program was helpful. The few people who indicated the program was not helpful indicated that this was because they knew information about their medication prior to the call.

EQ9: What are the components of the CMR provided by the UF COP pharmacists? (e.g., How is the CMR implemented?)

The components of the CMR can be understood through an examination of the context of the calls, the CMR delivery, and the pharmacists' skills. Broadly looking at the context of the calls, the sound quality and phone connections were good. Some participants were sometimes resistant and did not readily engage with pharmacists. Other participants were talkative and sometimes spoke at length on topics only peripherally related to health. Throughout the calls there was sometimes confusion and difficulty understanding on both the part of the pharmacists and participants. Often the pharmacists sought clarification and ensured there was understanding.

The CMR was structured and began with pharmacists having participants gather information about their medication. During the call the pharmacists verified the participants' medications as well as their adherence. There were discussions about the side effects of the medication. Pharmacists asked participants about elements of their lifestyle that impact health and also provided basic health information. At times pharmacists provided advice related to participants' health and medication. Pharmacists solicited participants' questions and thoroughly answered them.

There were variations in pharmacists' skills, yet all pharmacists used active listening skills and different types of questions to engage participants. Pharmacists used normalization when discussing sensitive topics with participants. Throughout the CMRs, participants shared hardships and challenges in their lives and pharmacists provided support and encouragement. Sometimes there were in-depth conversations during the CMR. In the calls, pharmacists did not consistently give the disclaimers that the call was being recorded for training and evaluation purposes and did not consistently stress the voluntary nature of the MTM program. Also, the quality assurance questions at the end of the CMR were not consistently asked.

Qualitative Evaluation Limitations

This qualitative analysis relies on the audio recordings from UF COP. While examining the intervention provides opportunities to understand how the CMRs were conducted, there are limitations to using secondary data. The primary limitation is that the quality assurance questions were not consistently asked during the calls and the quality assurance questions were limited in scope. The inconsistency in asking the quality assurance questions as designed impacted the ability to answer EQs 6-8. As noted in Appendix II in the detailed description of the qualitative methods, years two and three of the evaluation will be substantially different due to the increased quality assurance questions asked at the end of the CMR and during the 30 to 60-day follow-up calls.

An additional limitation was several audio files selected for the evaluation were not available. When this occurred, additional files replaced the audio files. After all of the audio files were transcribed, the ET learned that some of the dates on the list may have been incorrect; thus, the files may have been available yet not found due to searching on the date listed rather than the date the call occurred.

Finally, the CMRs that were evaluated were all over 20 minutes long. It is possible and perhaps likely that there are differences among the shorter calls. The selected calls were chosen because they were more likely to be substantive as compared to shorter calls, but this may have resulted in some selection bias.

Qualitative Evaluation Recommendations and Next Steps

The following are recommendations resulting from the qualitative evaluation of the MTM Program:

1. Ensure participants are informed that the phone call is being recorded for the purpose of training and evaluation.
2. Ensure participants are informed that their participation in the CMR is voluntary and their decision to participate in the CMR program and any information they provide to the pharmacist does not impact their insurance coverage.
3. Ensure participants are asked the quality assurance questions at the end of the CMR and in the 30 to 60-day follow-up. Ideally, questions should be asked by a neutral third party (not the pharmacist) to encourage participants to provide honest feedback about the MTM program.

4. Enhance training of UF COP pharmacists focusing on clinical communication including active listening; engagement; probing for additional information; and effectively interviewing resistant and talkative participants.
5. Increase the proportion of participants who receive the 30 to 60-day follow-up calls.
6. Increase the proportion of participants who receive the medication list (e.g., return receipt US Postal Service).

Future evaluations of the MTM Program could include:

1. An examination of brief CMR calls with a comparison of shorter and longer CMR calls.
2. A case study analyzing specific CMRs cases meeting a criteria of clinical significance (i.e., drug interactions, low levels of adherence, duplicate prescription, overuse of medication, etc.).
3. A comparison of the transcripts of the CMR calls with the UF COP manual for the MTM program and/or best-practice standards to determine specific areas where the MTM program could improve.

Appendix I Detailed Quantitative Methods

Data Sources and Preparation

Agency Administrative Data

Administrative data for this report include Agency pharmacy claims and encounters as well as demographic and program eligibility information for Medicaid recipients who were members of the MEDS-AD Waiver MEG1 population at any time between June 1, 2014 and May 31, 2016. Eligibility and enrollment durations were determined using the date spans associated with MEDS-AD program codes assigned via the aid category in the program eligibility file. Recipients are included in the study population based on criteria defined by the MEDS-AD Waiver and outlined in the Introduction. Enrolled days are calculated on a month-by-month basis. The administrative data used for this report are believed to represent nearly all MEDS-AD recipient pharmacy utilization for the period June 1, 2014 to December 31, 2015. Because valid adherence measures require all pharmacy records for a given observation window, analysts did not exclude claims/encounters on a monthly basis. Instead, analysts completely excluded anyone with any observed month(s) of dual Medicare eligibility due to apparent missing pharmacy data for these individuals; conversely, analysts included months where long-term care (LTC), Hospice, or HCBS service utilization was observed because recipients who received these services did not appear to be missing pharmacy claims during those months. These decisions maintained the validity and reliability of recipients' adherence measures, whereas excluding claims on a monthly basis due to alternative program use would lead to invalid and unreliable adherence measures.

UF COP Intervention Data

Additional data sources utilized include the UF COP MTM participant list for Cohort 5, individual patient data collected from recipients in the MTM-P group, and UF COP quarterly reports for the intervention year provided to the Agency. The ET used the participant lists to assign recipients to the MTM-P group, while medication adherence levels and medication change recommendation/resolution information was extracted from the other UF COP files.

UF COP patient data for Cohort 5 was provided via four Excel files. 1) The Completed Activities report details all contact with MTM-Ps as well as MEG1 population members who declined participation or could not be reached after attempted contact. For MTM-Ps, this report includes information on when the MAP was mailed and any education/counseling pharmacists provided to participants with identified lifestyle issues, such as smoking, or manageable chronic illness(es), such as hypertension. 2) The Clinical Information file contains open-ended, long-form descriptions of the CMR and medication reviews. These

reviews are conducted quarterly by UF COP pharmacists for each MTM-P. There are 4 records for each participant in this file, corresponding to the CMR completion date and the dates of the three subsequent quarterly reviews. 3) The Medications file contains prescription-level information on MTM-Ps' adherence levels for each medication identified via a pharmacy claims data search and/or during the CMR. 4) Finally, the Drug Therapy Problem report contains participant-level records of any identified medication issues, e.g., drug-drug interactions or duplicate therapy, and a binary indicator for presence/absence of a corresponding resolution. Participants may have multiple records in this file if the pharmacist identified more than one medication problem. A problem/resolution was first assigned to a quarter if it occurred within plus/minus one week of the date of a participant's CMR or the first date of the subsequent quarters as recorded in the clinical info file. If assignment did not occur through this method, then an activity was assigned to a given quarter if it took place on or after its start date but before the first date of the following quarter.

Study Participants and Processes

Recruitment of the Intervention Population

Selection of recipients covered by the waiver to participate in the intervention is a multistep process involving Agency staff, the UF COP, and consent at two points in time by targeted Medicaid recipients. The word "selection" refers to processes used by the Agency to produce a list of 3,600 MEG1 recipients for initial contact from which a subset of these recipients provide their consent to participate in the MTM intervention group. In essence, the Agency and UF COP does not "select" MTM participants; rather, they self-select into the intervention. Recipients who opt into the intervention and ultimately complete a CMR form the study's nominal MTM-P population. All participants were selected from an original query of recipients who were eligible for the MEDS-AD waiver during the spring of 2015.

Selection Process

Steps in the selection process were as follows. Step 1: Agency staff created a list of recipients currently enrolled in the MEDS-AD MEG1 population in the spring (March to May) before the start of the intervention year on June 1st. Efforts were made to screen ineligible recipients, e.g., Medicare beneficiaries, from the original query. Step 2: Pharmacy staff contacted recipients on the "original query" list to obtain consent for later telephone contact by the UF COP for the purpose of offering the opportunity to participate in the MTM intervention. UF COP staff used contact information for recipients giving consent at Step 2 to schedule a CMR. Step 3: UF COP staff made telephone contact(s) with

recipients, confirmed their continued interest and consent to participate, and scheduled a future telephone CMR, most of which took place in August or September of the intervention year. Only recipients who ultimately complete a CMR are designated as MTM-P.

Intervention Process

Steps in the intervention processes were as follows. Step 1: Complete the CMR over the telephone with a UF COP pharmacist. Occasionally, CMRs were conducted during the scheduling telephone call, but most often CMRs were completed in August or September of the intervention period. Step 2: Any problems identified by UF COP staff were discussed with the participants, and the CMR document and recommendations were typically faxed to each recipient's physician. A copy of the MAP was also sent to the recipient unless declined. Step 3: UF COP staff followed up with MTM program participants by telephone and/or review of electronic claims records at least every 90 days to identify any resolutions to previous recommendations or any new problems. The intervention period ends May 31st of the following year.

Inclusion-Exclusion Criteria Detail (EQ2 and EQ5 only)

The study population was pared down for EQ2 and EQ5 using the following criteria.

- Step 1: Identify the nominal study population using the Agency's Aid Category codes for those listed in original query the Agency sent to UF COP for the purposes of recruiting MEDS-AD eligible recipients into the intervention group.
- Step 2: Pharmacy records from before June 1, 2014 and after December 31, 2015 were removed.
- Step 3: Persons who died before the end of the claims observation period (December 31, 2015) were removed.
- Step 4: Persons with no MEDS-AD program enrollment during the intervention study period were removed (all individuals had at least one month of MEDS-AD enrollment during the pre-intervention period).
- Step 5: Dual eligibles with observed Medicare eligibility in the pre-intervention period and/or intervention period were removed due to concerns about incomplete pharmacy records for these individuals.
- Step 6: Individuals who participated in previous MEDS-AD MTM interventions were excluded.

Table 21. Criteria and steps used to identify recipients for inclusion in and exclusion from the evaluation study population for EQs 2 and 5, Florida MTM program evaluation, June 1, 2014 - December 31, 2015

Step	Inclusion-Exclusion Condition	Filtering Variable Applied	Filtering Variable Source	Action Description	Domain	Why is Action Taken?	Number of Recipients Identified*
1	Initial study population (inclusion)	Aid Category	Original Query with Agency program codes	Include if in Original Query and MEDS-AD program code present	Study population selection	Identify MEDS-AD study population and MTM-P & -NP groups	3,600
2	Pharmacy claims (inclusion)	Prescription fill date	Pharmacy claims records	Include any Rx fills between 06/01/2014 - 12/31/2015	Study design requirement	Keep all prescriptions filled during defined study periods	3,600
3	Death (exclusion)	Date of death	Agency demographic file	Exclude if death prior to 01/01/2016	Study population selection	Number of deaths is small; different traits than overall study population	134
4	No MEDS-AD enrollment in SP-INT (exclusion)	Aid Category	Agency program codes	Exclude if no MEDS-AD enrollment between 06/01/2015 - 12/31/2015	Study population selection	No adherence calculated for those without any MEDS-AD enrollment in intervention claims period	245
5	Medicare enrollment (exclusion)	Benefit Plan	Agency program codes	Exclude if any Medicare enrollment between 06/01/2014 - 12/31/2015	Study design requirement	Most of those enrolled in Medicare have no reported Rx fills in the pharmacy claims file once enrolled (results in invalid adherence scores)	259
6	Previous intervention participation (exclusion)	Crossover Participant	UF-COP previous MTM-P files	Exclude if received intervention in previous cohort	Study design requirement	Cannot measure treatment effect if recipient participated in prior MTM study	10

*Recipients (60 in total) who meet more than one exclusion restriction are double-counted in the final column of steps 3-6.

Analysis

Descriptive analysis is useful for identifying the range and distribution of measured values in the study population. It is also useful for examining how ostensibly similar the intervention and comparison groups are at baseline and post-intervention on some measure of interest. The tables in this appendix provide information in an easy to use format that can be compared to other Agency data for corresponding measures. The analysis in this report utilized simple descriptive comparisons for selected adherence and demographic measures from Medicaid administrative data with intermittent tests for statistical differences between the defined study groups using chi-squared tests and t-tests, as appropriate.

Medication Adherence Measures

The quantitative analysts initially intended to use standard risk adjustment and medication adherence software to automatically calculate adherence scores for each participant and non-participant; however, this software requires both medical and pharmacy claims, and they only had access to the study population's pharmacy records. Accordingly, they manually calculated Medication Possession Ratios (MPRs) and the PDC for each patient in the entire study population after applying the inclusion-exclusion criteria outlined in Table 21 above. These techniques drew from a publicly available program in Statistical Analysis Software (SAS).[4]

MPRs and PDCs are both proxies of adherence. MPR is the ratio of the sum of the number of days supplied for a given medication to the claims interval for that medication, while PDC is the number of days covered over the claims interval. Basically, the PDC metric eliminates overlapping days caused by patients filling their medications early, crediting the patient with completing a fill before beginning the next, potentially mitigating overstatement of compliance that may occur by just totaling a medication's days' supply. For the purposes of this report, both measures are calculated from the first fill date through the last date of supply for a given medication.

The MPR and PDC metrics are calculated for each medication that an individual takes for a chronic condition, so if the classification scheme does not identify at least one chronic condition for a given individual, then the code will not calculate either adherence score for that person (see Table 22 below for a breakdown of which medications were included in the adherence measure calculations based on the American Society of Health-Systems Pharmacists' American Hospital Formulary Service (AHFS) classification scheme). The analysts used UCSD School of Medicine's MRX classification scheme to identify chronic condition presence based on the NDC codes of the medications reported in patients' claims records (see Table 23 below for the list of chronic conditions). UCSD developed this component of their Chronic Illness and Disability Payment System risk adjustment system to enable a risk adjustment model based on pharmacy data alone.

Both adherence measures are computed separately for the pre-intervention and intervention periods, the aggregate results of which are presented in Tables 8 and 9 in the main body of the report. For the purposes of this report, patients' adherence measures represent an average of their medication-level MPRs to determine their overall MPR scores and an average of their PDC for each medication to determine their overall PDC scores. The reader should note that MTM-NPs' pre-intervention period

[4] http://pharmasug.org/download/sde/sd2016/PharmaSUG_SD2016SDE_07_Leslie.pdf

spans from 06/01/2014 through 05/31/2015, and their intervention period starts on 06/01/2015 and ends on 12/31/2015. In contrast, to ensure a valid measure of the treatment effect, MTM-Ps' pre-intervention period spans from 06/01/2014 through the last day prior to their CMR, while their intervention period starts on the first day of their CMR and ends on 12/31/2015. For both groups, there is a shorter observation window for the intervention period to minimize the effects of claims run-out.

Table 22. Medications included in the MPR and PDC adherence measure calculations per AHFS classification scheme

AHFS Classification	Count Included RXs	Count Excluded RXs	Count All RXs	Percentage Included Adherence Measures	Percentage Excluded Adherence Measures
Anti-infective Agents	13,798	2,639	16,437	83.9%	16.1%
Antihistamine Drugs	431	3,937	4,368	9.9%	90.1%
Antineoplastic Agents	1,736	249	1,985	87.5%	12.5%
Autonomic Drugs	12,113	3,646	15,759	76.9%	23.1%
Blood Derivatives	-	-	-	-	-
Blood Formation, Coagulation, & Thrombosis	5,761	1,058	6,819	84.5%	15.5%
Cardiovascular Drugs	44,224	7,455	51,679	85.6%	14.4%
Cellular Therapy	-	-	-	-	-
Central Nervous System Agents	50,954	26,048	77,002	66.2%	33.8%
Contraceptives	-	3	3	0.0%	100%
Dental Agents	-	1,107	1,107	0.0%	100%
Devices	-	5,467	5,467	0.0%	100%
Diagnostic Agents	-	2,558	2,558	0.0%	100%
Disinfectants	-	-	-	-	-
EENT Preparations	4,332	2,496	6,828	63.4%	36.6%
Electrolytic, Caloric, and Water Balance	7,433	4,716	12,149	61.2%	38.8%
Enzymes	-	-	-	-	-
Gastrointestinal Drugs	13,341	5,262	18,603	71.7%	28.3%
Gold Compounds	-	-	-	-	-
Heavy Metal Antagonists	-	23	23	0.0%	100%
Hormones and Synthetic Substitutes	19,038	2,791	21,829	87.2%	12.8%
Local Anesthetics	-	13	13	0.0%	100%
Miscellaneous Therapeutic Agents	1,676	857	2,533	66.2%	33.8%
Oxytocics	-	-	-	-	-
Pharmaceutical Aids	-	2,713	2,713	0.0%	100%
Radioactive Agents	-	-	-	-	-
Respiratory Tract Agents	4,636	2,184	6,820	68.0%	32.0%
Serums, Toxoids, and Vaccines	-	239	239	0.0%	100%
Skin and Mucous Membrane Agents	168	10,980	11,148	1.5%	98.5%
Smooth Muscle Relaxants	668	80	748	89.3%	10.7%
Vitamins	1,381	3,330	4,711	29.3%	70.7%
Unclassified	-	90	90	0.0%	100%
Total	181,690	89,941	271,631	66.9%	33.1%

Table 23. List of chronic conditions identified using UCSD's MRX system

Alcoholism/Substance Use	Infection, high
Alzheimer's	Infection, medium
Asthma/COPD	Infection, low
Attention Deficit Disorder	Inflammatory/Autoimmune Disorder
Burns	
Cardiac Disorder	Insomnia
Coagulation Disorder	Iron Deficiency
Cystic Fibrosis	Irrigating solution
Depression/Anxiety	Liver Disease
Diabetes	Malignancies
EENT Disorder	Multiple Sclerosis/Paralysis
ESRD/Renal Disorder	Nausea
Folate Deficiency	Neurogenic bladder
CMV Retinitis	Osteoporosis/Pagets
Gastric Acid Disorder	Pain
Glaucoma	Parkinson's/Tremor
Gout	Prenatal Care
Growth Hormone Deficiency	Psychotic Illness/Bipolar Disorder
Hemophilia/von Willebrand	Replacement solution
Hepatitis	Seizure Disorder
Herpes	Thyroid Disorder
HIV	Transplant
Hyperlipidemia	Tuberculosis

Appendix II Detailed Qualitative Methods

An Overview of the Qualitative Evaluation Team Effort

This qualitative evaluation of the MTM program uses audio recording of complete CMR calls conducted by UF pharmacists as well as quality assurance questions asked during CMR calls and 30 to 60-day follow-up calls. Thus, the evaluation examines the actual intervention and can increase understanding of the components of the CMR as well as participants' perceptions of the program.

Audio files of the CMR calls and the quality assurance questions were transcribed verbatim by the evaluation team. Then, using qualitative data analysis software, the evaluation team conducted a thematic analysis of the transcripts to answer the following evaluation questions: (E6) What do participants perceive to be the most valuable components of the MTM program? (E7) How do participants perceive that the CMR assists them? (e.g., How does the CMR impact participants' ability to understand medications, take a more active part in their care, and understand the questions to ask their doctor or when to contact their doctor?) (E8) How do participants rate the overall care they experienced in the MTM program? And (E9) What are the components of the CMR provided by the UF COP pharmacists? (e.g., How is the CMR implemented?).

As the qualitative evaluation relied on the audio files of a waiver period (June 1, 2015 through May 31, 2016) that occurred before the qualitative evaluation was conceptualized, the quality assurance questions were limited. In subsequent waiver periods more extensive questions will be asked to participants.

Data Sources

All recordings used are secondary data attained from AHCA and originates from the COP UF. UF COP recorded CMR calls and the 30 to 60-day follow-up calls for the purpose of training and evaluation. The audio files were provided to the evaluation team for the purpose of evaluation as secondary data.

The three data sources for the project include:

1. Recordings of the CMR call conducted by UF COP pharmacist with participants
2. Recordings of the quality assurance questions completed at the end of the CMR by UF COP pharmacists
3. Recordings of the quality assurance questions completed at the end of the 30 to 60-day follow-up by UF COP pharmacists

Table 24 indicates the data sources used to answer each of the EQ.

Table 24. Data sources and evaluation questions.

Evaluation Question	Data Source(s)
EQ6	1) Recordings of the quality assurance questions completed at the end of the CMR 2) Recordings of the quality assurance questions completed at the end of the 30 to 60-day follow-up.
EQ7	
EQ8	
EQ9	Recordings of the CMR call conducted by UF COP with participants

For the first year of the current evaluation project (waiver period from June 1, 2015 through May 31, 2016), UF COP pharmacists asked the following quality assurance questions at the conclusion of the CMR calls:

1. Did you find this appointment helpful?
2. Did this interview help clarify any concerns you may have had with your medication?

Additionally, UF COP pharmacists asked the following quality assurance questions during the 30 to 60-day follow-up calls:

1. Did you find the mailed documents to be helpful?
2. Did participating in the phone call increase your understanding of your medication regimen?

For the second and third years of the evaluation project (waiver period from June 1, 2016 to September 30, 2018), UF COP has agreed to incorporate the following additional interview questions into their workflow and will attempt to have these questions handled by someone other than the pharmacist completing the CMR (i.e., neutral party):

1. What do you see as the best part of the program?
2. How did this review of your medications help you?
3. How would you rate the overall care that you experienced with the medication program? (Very Good, Good, Fair, Poor, Very Poor)

Likewise, for the second and third years of the project (waiver period from June 1, 2016 to September 30, 2018), UF COP has agreed to have pharmacists ask the following calls during the 30 to 60-day follow-up calls:

1. What do you see as the best part of the program?
2. How did this review of your medications help you?
3. How would you rate the overall care that you experienced with the medication program? (Very Good, Good, Fair, Poor, Very Poor)
4. Did you find the mailed documents to be helpful?
5. Did participating in the phone call increase your understanding of your medication regimen?

Sample Selection

The evaluation team randomly selected a sample of CMR calls that were over 20 minutes long to transcribe verbatim. The decision to focus on longer calls was both methodological and pragmatic. Longer calls were chosen to provide more opportunities for the evaluation team to understand pharmacist and participant interactions during the CMRs. Additionally, longer calls were more easily identified in the pool of over 6,000 audio files provided to the evaluation team. The evaluation team purposively selected 33 CMRs as well as the randomly selected quality assurance questions asked at the conclusion of 47 CMRs and during 36 of the 30 to 60-day follow-up calls.

Data Management

The original recordings obtained from the study's AHCA Contract Manager were delivered by Primary Investigator to Co-Primary Investigator at FSU's campus. The data, saved on two DVDs, are stored in a locked office in a locked filing cabinet. Copies of the digital audio recordings were placed on two workstations in a call center described below.

All digital recordings and transcriptions are stored on workstation computers that are 1) operating on a local network (and not connected to any outside network), 2) only used by research study personnel, 3) located in a locked call center, inside an office suite and building that are locked after hours, and 4) backed up weekly to separate storage media which is kept in locked cabinet in secure call center. All research study personnel involved completed a Level 2 background check, Human Subjects Training, and specific training about data management. The data management follows the Privacy Compliance Plan.

The audio files were only named with alpha-numeric codes and the date when the file was recorded. The evaluation team received over 6,000 audio files of varying length and had to identify the CMR and 30 to 60-day follow-up calls that the evaluation team transcribed. This was a lengthy and time consuming process. The co-PI had a spreadsheet containing participants' names; the pharmacist's name; the date that the CMR or 30 to 60-day follow-up calls occurred; and the length of the telephone call.

Using this information, she searched the date which the call occurred and listened to the audio files until the pharmacist and participants' names could be identified. Then the co-principal investigator (co-PI) recorded the alpha-numeric file name in a table so that the research assistants (RAs) could identify and transcribe the audio file.

RAs transcribed the audio files verbatim into word documents removing any the names, address, data of birth, and other identifying information. All transcriptions were imported into the NVivo10, the qualitative data analysis software, which the evaluation team used to conduct the analysis.

Weekly, the doctoral RA backed up all transcriptions and NVivo files to an encrypted hard drive that is stored in a locked filing cabinet in the locked call center.

Qualitative Data Analysis Software

The evaluation team used NVivo10, qualitative data analysis software, to analyze the transcripts. The software served as a tool for analysis, yet all analytic decisions (e.g., the prevalence or relevance of a theme) remain with the evaluation team. A common metaphor explaining the role the software has is that PowerPoint no more creates a presentation than NVivo conducts an analysis. Qualitative data analysis software was simply a tool to assist the evaluation team in the analysis of data.

Data Analysis

To analyze the data from the interviews with the MEDS-AD MTM participants, the evaluation team conducted a thematic analysis which allowed the evaluation team to identify themes (patterns or meanings) within the data and the relationships among the themes. There are six phases of conducting thematic analysis: 1) becoming familiar with the data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) producing the report. Data analysis is an iterative recursive process and the phases of a thematic analysis are not necessarily linear.

Becoming Familiar with the Data

The process of becoming familiar with the data began during the transcription process. RAs transcribed and reviewed the transcriptions of the audio files. The co-PIs read the transcripts and examined the data using NVivo software.

Generating Initial Codes

The co-PIs of the qualitative evaluation team and the doctoral RA worked independently to identify initial codes, which can be conceptualized as succinct labels, within the two transcripts.

Throughout this process, they wrote notes about their thoughts and understanding of the codes and potential themes.

Searching for Themes

The evaluation team met to discuss the initial codes evaluation team members had individually identified. The discussion included how the initial codes are theoretically connected and how they answer the research questions. The team discussed the broader patterns of meaning (themes) in the data. In the meeting, the evaluation team developed an initial list of codes for each question. Afterward, evaluation team members wrote notes about their thoughts on the codes and the emerging themes. An initial list of codes and their definitions was created. Each evaluation team member reviewed the list of codes and consensus was reached on the definitions. The codes and their definitions were entered into NVivo10, the qualitative data analysis software used on the project.

Reviewing Themes

Using NVivo software, the RAs coded the data using the codes and definitions created in the evaluation team meeting. As necessary, additional codes were created during the process. Through constant comparison, the evaluation team explored how well the themes fit the data. Reviewing themes involved checking themes against one another and the data to determine the coherent story in the data. Themes were refined and combined as necessary to ensure they represented the data. Throughout the review process, the evaluation team wrote notes about their thoughts of the themes and insights about the data. Additionally, the evaluation team discussed the themes within the data. NVivo software query functions were used to explore the prevalence and patterns in the themes. The evaluation team created a framework to understand the data based on the themes. This includes a detailed exploration of each theme and determining the "story" or relevance of each theme.

Defining and Naming Themes

The co-PIs and doctoral RA met to discuss the coding and determined the final themes. Through a series of discussions, they reached consensus on the themes and how they were named and described.

Producing the Report

The co-PI and the doctoral RA wrote the report based on the findings. Throughout the process, they reviewed the data and incorporated information from the calls as examples of themes.

Strategies for Rigor

The rigor of qualitative research increases through triangulation of data and methods. Triangulation seeks corroboration between at least two data sources and interpretation. Triangulation can include the use of multiple types and sources of data. The various types and sources of data in this study add to the clarity and verification of interpretations.

This qualitative portion of the evaluation incorporated multiple types of triangulation. There were multiple sources of data with audio recording of different UF COP Pharmacists with various MTM participants. The recordings were at different time points—during the CMR as well as during the 30 to 60-day follow-up calls. There were also multiple evaluation team members involved with the evaluation. During the data analysis process, the evaluation team met regularly to discuss their understanding of the data. The discussions provided opportunities to thoroughly examine the data. Since qualitative data analysis software was used, the evaluation team could conduct in depth examination of the data and relationships among the themes.

Another strategy for rigor is that the findings of the qualitative evaluation are contextualized with the findings of previous evaluation of the MEDS-AD MTM Demonstration project. Additionally, at the completion of the qualitative component of the evaluation, data and findings were integrated with the quantitative component of the MEDS-AD MTM Demonstration project evaluation.

Appendix III EQ2 Models

The evaluation team speculated that observed differences in mean MPR and PDC scores were likely due to systematic differences in observation length imposed by the availability of data in the intervention period, the timing of CMRs, and for some study members, abbreviated MEDS-AD eligibility spans. Therefore, the analyst first ran a fully specified model at the recipient-medication level, predicating adherence from study group membership (MTM-P vs. MTM-NP), time period (SP-INT vs. SP-PRI period), study group by time period, and observation length for each medication, while accounting for repeated measurements on study members with multiple medications. The analyst then performed backwards selection, successively eliminating each non-significant explanatory variable. This modeling process was performed separately for the MPR and PDC metrics. The models confirm the evaluation team's speculation: any systematic differences in adherence scores seem to result from differences in observation length.

MPR

Table 25. Fully specified General Estimating Equation logistic regression model for EQ2 MPR scores, Florida MTM Program evaluation, June 1, 2014 - December 31, 2015.

Parameter	EST	SE	95% LCL	95% UCL	Pr > |Z|
Intercept	2.6316	0.0263	2.5799	2.6832	<.0001
MTM-P	-0.0488	0.112	-0.2683	0.1707	0.663
MTM-NP	0	.	.	.	.
SP-INT	-0.0517	0.0269	-0.1044	0.001	0.054
SP-PRI	0	.	.	.	.
Interaction Term*	0.095	0.1251	-0.1502	0.3402	0.448
Observation length	-0.01	0.0002	-0.0103	-0.0096	<.0001

*Change in MTM-P outcomes between study periods versus the change in MTM-NP outcomes between periods.

Table 26. Final General Estimating Equation logistic regression model for EQ2 MPR scores, Florida MTM Program evaluation, June 1, 2014 - December 31, 2015.

Parameter	EST	SE	95% LCL	95% UCL	Pr > |Z|
Intercept	2.604	0.0226	2.5597	2.6482	<.0001
Observation length	-0.01	0.0002	-0.0103	-0.0096	<.0001

PDC

Table 27. Fully specified General Estimating Equation logistic regression model for EQ2 PDC scores, Florida MTM Program evaluation, June 1, 2014 - December 31, 2015.

Parameter	EST	SE	95% LCL	95% UCL	Pr > |Z|
Intercept	2.5755	0.0265	2.5236	2.6275	<.0001
MTM-P	-0.0796	0.1079	-0.2911	0.1319	0.4606
MTM-NP	0	.	.	.	.
SP-INT	-0.0349	0.0263	-0.0863	0.0166	0.1843
SP-PRI	0	.	.	.	.
Interaction Term*	0.0821	0.1258	-0.1644	0.3286	0.5139
Observation length	-0.0109	0.0002	-0.0113	-0.0105	<.0001

*Change in MTM-P outcomes between study periods versus the change in MTM-NP outcomes between periods.

Table 28. Final General Estimating Equation logistic regression model for EQ2 PDC scores, Florida MTM Program evaluation, June 1, 2014 - December 31, 2015

Parameter	EST	SE	95% LCL	95% UCL	Pr > |Z|
Intercept	2.5548	0.0238	2.5081	2.6015	<.0001
Observation length	-0.0109	0.0002	-0.0113	-0.0105	<.0001

College of Medicine

College of Social Work

Florida State University